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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Edward M. Chen, Judge

GUARDANT HEALTH, INC.,	)	
	)	
Plaintiff,	)	
	)	
VS.	)	Case No. 3:21-cv-04062 EMC
	)	
NATERA, INC.,	)	
	)	
Defendant.	)	
	)	

San Francisco, California  
Monday, February 26, 2024

TRANSCRIPT OF REMOTE ZOOM PROCEEDINGS

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1 **Monday - February 26, 2024**2 **2:32 p.m.**3 **P R O C E E D I N G S**4 **---oo---**5 **THE CLERK:** This court is now in session, the  
Honorable Edward M. Chen presiding.6 Court is calling the case **Guardant Health, Inc. v. Natera,**  
7 **Inc., Case No. 21-4062.**8 Counsel, please state your appearance for the record,  
9 beginning with the plaintiff.10 **MR. PERLOFF:** Good afternoon.11 **MS. KELLER:** Good --12 **MR. PERLOFF:** Saul Perloff on behalf of **Guardant**  
13 **Health.** With me from Shearman & Sterling today is Christopher  
14 **LaVigne.**15 **THE COURT:** Okay.16 **MS. KELLER:** Good afternoon, Your Honor.17 **THE COURT:** All right. Good afternoon.18 **MS. KELLER:** Jennifer Keller of Keller Anderle on  
19 behalf of **Guardant Health.**20 **THE COURT:** All right. Thank you, Ms. Keller.21 **MR. SCOLNICK:** And good afternoon, Your Honor. Chase  
22 Scolnick on behalf of **Guardant Health.**23 **THE COURT:** All right. Thank you, Mr. Scolnick.24 **MR. JOHNSON:** Good afternoon, Your Honor. Kevin  
25 Johnson on behalf of **Natera.** And with me -- depending upon

1 what issues you want to address -- there may be a few of us  
2 speaking, Your Honor. We have Valerie Lozano, Margaret Shyr,  
3 Vickie Maroulis, Brian Cannon, and Andrew Bramhall.

4 **THE COURT:** All right. I don't know if everybody will  
5 get a chance to speak, but we'll see.

6 **MR. JOHNSON:** Yeah.

7 **THE COURT:** Okay.

8 All right. First thing we should talk about is the trial  
9 date. So I did receive the declarations. Perhaps I can get an  
10 update whether there's been any more word about the  
11 presentation dates, because there was a range of dates that  
12 were suggested, and I don't know whether anything is new.

13 **MR. SCOLNICK:** Thank you, Your Honor.

14 We have no updates since Friday. But I would like to  
15 provide some additional information. In preparing for today's  
16 hearing, we were looking through some of the most recent  
17 materials that Natera submitted to the Court, including their  
18 latest updated trial witness list. And we learned that from  
19 that list, they intend to have Dr. Aleshin and Mr. Moshkevich  
20 also testify about the COBRA Study.

21 So if -- if the Court's going to allow the COBRA Study  
22 into evidence, and if the Court's going to allow them to  
23 testify, then of course we would need to seek their documents  
24 regarding the COBRA Study and also take their depositions about  
25 that topic. This is not something that was noticed earlier,

1 before the most recent submission.

2           **THE COURT:** All right.

3           **MR. SCOLNICK:** And, in addition, Your Honor, there are  
4 also -- something we didn't raise -- we referenced them in  
5 passing -- some of the other studies that were referenced in  
6 Dr. Hochster's supplemental report. And those would include  
7 the bestoke [phonetic] -- BESPOKE -- excuse me -- and  
8 CIRCULATE-Japan Study. Those studies are not published. They  
9 are interim studies. And Dr. Hochster seeks to opine on them.  
10 So if he's going to be permitted to do so, we would seek  
11 discovery on that, as well.

12           **THE COURT:** All right.

13           Response?

14           **MR. JOHNSON:** Well, Your Honor, this is -- we had a  
15 meet and confer process where we talked about the discovery  
16 that they wanted. This is the first time we're hearing that  
17 they want additional discovery, beyond all the other categories  
18 that they provide in the last telephone call conference.

19           You know, I don't think there's any real surprise that  
20 we're calling our -- Dr. Moshkevich and Dr. Aleshin. And, you  
21 know, the -- they're on our will-call list. In fact, I want  
22 to -- and I'm -- this is something we do want to address. They  
23 want to call each of these witnesses in their case in chief.  
24 They want to take them out of order. They don't want them to  
25 testify in our case. They want them to testify in their case.

1       So, you know, as we said in -- the last time -- we think  
2 we're -- we're fine with some limited discovery. And the --  
3 you know -- and just because Your Honor raised it, you know, I  
4 mean, when I read the declarations -- and I'm not going to  
5 comment on them -- but this is a one-day meeting that they're  
6 talking about. And they're setting aside a full month for --  
7 you know, of saying they're not available -- for a one-day  
8 meeting.

9       Your Honor knows -- you know, we can -- we firmly believe  
10 we can take that into consideration and -- you know, as a trial  
11 date that appears in sometime in April or May -- to take into  
12 account if, in fact, their schedule is set for sometime during  
13 those -- during those days.

14       I will tell you, on a recent earnings call, that they --  
15 that they -- that Guardant identified that the hearing they  
16 thought would occur with the FDA would occur at the end of the  
17 second quarter of the year, which since tells us and told the  
18 public that that's closer to June. So I'm not sure what the  
19 real date is here. And we're all sort of, you know, working  
20 off of something that may get scheduled at some point or may  
21 not get scheduled at some point. But we're -- we're in the  
22 time frame that we care about.

23       At the end of the day, we're willing to agree to some  
24 limited discovery. And I need to go back and check on --  
25 specifically with respect to Dr. Moshkevich and Dr. Aleshin.

1                   **THE COURT:** All right. Well, we'll talk about the  
2 scope of discovery.

3                   What about this indication that this meeting may not occur  
4 until the second quarter? Is there a possibility this could  
5 occur in -- at a later date -- beyond the time frame that was  
6 indicated?

7                   **MR. SCOLNICK:** No, Your Honor. The latest information  
8 that we have is that it is going to be between the days we set,  
9 which I believe it's April 25th and the end of May. I believe  
10 that we said in the earnings call that it would happen sometime  
11 in late second quarter, which is consistent with that, and also  
12 taking a conservative approach.

13                  So, yes, it is a one-day meeting, but we don't know when  
14 that date is, which is what is providing the complication here.  
15 In addition, as we note in our declarations -- the founders  
16 did -- it's going to take extensive preparation. And this is  
17 probably one of the most important days in Guardant's history,  
18 for the reasons we set forth.

19                  And, again, if -- we were prepared to go forward with  
20 trial as currently set. And it's not our -- we're not the ones  
21 causing the delay here. It's opposing Counsel and it's Natera.  
22 So if that's going to be -- if we're going to allow this  
23 additional evidence in, then we need time to prepare. And,  
24 unfortunately, our founders are not -- not available during  
25 this period of time.

1                   **MR. JOHNSON:** Your Honor, I just want to read from the  
2 February 23rd earnings call. And it says, quote, "In our  
3 recent discussions, the FDA has informed us that the meeting  
4 date will now likely take place in late Q2 as they continue to  
5 work to fill the remaining vacant advisory seats on the panel."

6                   So "late Q2," to us, suggests could be as late as June.  
7 That's -- so, you know, I'm not -- I think everybody would  
8 agree, there is no date yet. And they've -- as recently as  
9 just a few days ago, they told the public, in our earnings  
10 call, it could be as late as Q2. And I think -- I don't think  
11 anybody really knows, is the point. And so finding one day  
12 that -- you know -- and I know we're trying to thread the  
13 needle to find the right time for the trial schedule. And our  
14 position is the dates that you identified the last time --  
15 April 29th -- you know, is the right date to start with.

16                   **THE COURT:** What -- well, let me ask, if -- is it a  
17 one-day meeting?

18                   **MR. SCOLNICK:** My understanding is that it's going to  
19 be a one-day meeting. But these things have bled over into  
20 two.

21                   And, in addition, Your Honor -- I apologize for not  
22 mentioning this earlier -- we did reach out to our expert --  
23 testifying expert -- on damages -- Mr. Malackowski -- and he's  
24 informed us that he also has a two-week trial between  
25 April 29th and through the week of May 6th. And he's expected

1 to attend throughout the trial in Delaware.

2           **THE COURT:** All right. Well, that's new. That was  
3 not brought to my attention; is that correct?

4           **MR. SCOLNICK:** I don't recall. I think we made  
5 mention that there was an additional conflict with our damages  
6 expert, but we've since been able to acquire more specific  
7 information.

8           **MR. JOHNSON:** Your Honor, that's correct. That's the  
9 first we're hearing of it, is right now.

10           **THE COURT:** All right. Let me -- let's put aside the  
11 start of the trial for a moment, and let's talk about the scope  
12 of discovery. What have we found out about the availability of  
13 the principal investigator, coauthors, et cetera, et cetera?

14           **MR. SCOLNICK:** Yes, Your Honor. So, as we expected,  
15 there would be a process at MD Anderson in order to secure  
16 his -- the principal investigator's testimony -- Dr. Morris.  
17 So we reached out to them. We've been engaging with them over  
18 the last few days. And they informed us that we need to  
19 complete forms and have a more complete and formal request.  
20 And we've done that.

21           We have also sent a subpoena out to Dr. Hochster. We're  
22 preparing and finalizing subpoenas to NRG. And we continue to  
23 investigate and further our efforts to secure an appropriate  
24 expert to respond to Dr. Hochster's supplemental report.

25           **THE COURT:** So subpoenas have not gone out yet to the

1 NRCG [sic]?

2                   **MR. SCOLNICK:** NRG? No, Your Honor. The only  
3 subpoena that's gone out, to my knowledge, is to Dr. Hochster.  
4 And, again, we've sent out the request, and we're following the  
5 instructions and procedures of MD Anderson.

6                   **THE COURT:** All right. And in terms of who needs to  
7 be deposed and what needs to happen, what -- did you all meet  
8 and confer about the scope of further discovery if I were to  
9 allow the COBRA trial to come in?

10                  **MR. SCOLNICK:** Your Honor, yes, we met and conferred  
11 before the last hearing. And we provided our estimate of what  
12 discovery we needed. Opposing Counsel did not provide us with  
13 any details, although we did learn those details -- some of  
14 them -- before the last call -- before the last hearing -- and  
15 then, at the hearing, they provided us some additional  
16 information. But, since then, we've not communicated.

17                  **THE COURT:** So you've not met and conferred to see if  
18 you can narrow your differences in terms of the scope?

19                  **MR. SCOLNICK:** Your Honor, yes, we did that on our  
20 call before the last hearing, pursuant to the Court's  
21 instructions, but not since.

22                  **THE COURT:** All right.

23                  **MR. CANNON:** Your Honor, Brian Cannon from Natera.  
24 I've subbed in for Kevin Johnson on this particular issue.

25                  We have not met and conferred since the last hearing, Your

1 Honor. And our position really is the same, which is what  
2 Mr. Johnson stated, which is some reasonable amount of  
3 discovery -- such as the deposition of Dr. Hochster -- and  
4 perhaps this additional third-party discovery is appropriate.  
5 But sort of the full-term scope of discovery that Guardant  
6 proposed on the last call, with rounds and rounds of reports  
7 and additional fact discovery, we feel is out of proportion to  
8 the supplemental report and will unduly delay preparation for  
9 trial.

10 **THE COURT:** Yeah. Well, we're sort of back where we  
11 were. I thought there was going to be an effort to meet and  
12 confer, with that view in mind, to see if that fairly broad  
13 scope could be narrowed to the parties' liking. But I guess  
14 that hasn't happened.

15 **MR. CANNON:** It has not, Your Honor. Like I said,  
16 we're open to some limited scope. But if the starting point is  
17 the amount of discovery that Guardant proposed in the last  
18 hearing, that is -- that is difficult. That's just undue in  
19 terms of its breadth.

20 **THE COURT:** Okay. Well, let me indicate a couple  
21 things. We will -- I want to go through some of these motions  
22 in limine, perhaps some of the evidentiary matters, and I have  
23 some comments about the jury instructions. So these are  
24 matters we're going to have to deal with, one way or the other,  
25 regardless of the time.

1       But I will say, at the outset, that whenever we start this  
2 trial, I have always allocated ten days to do this case. And  
3 what that means, in time, is that we'll probably have to devote  
4 one day to -- or a good part of the day -- to jury selection.  
5 So we essentially have, safely put, probably nine trial days.

6       And my trial hours are 8:30 to 1:30. And though I try to  
7 keep the breaks down to 15, 20 minutes, with no lunch break,  
8 when you have a jury -- and these days we're using neighboring  
9 courtrooms for public health reasons instead of the little  
10 cramped jury room usually for the jury assembly -- it takes  
11 time for them to kind of gather up and get into our courtroom.

12       So the reality, unfortunately, is we usually get about  
13 four hours -- maybe a little over four hours -- of testimony a  
14 day. What that means is we have 36 hours to try this case --  
15 nine days -- if you assume one day is devoted to jury  
16 selection. Maybe we'll get in a little extra. We'll see.

17       That comes down to 18 hours apiece. Your time estimates, I  
18 think on Guardant's side, was a little -- exceeded that a  
19 bit -- and it didn't include cross-examination time, nor did it  
20 include time for opening statements and closing arguments.

21       So just a warning to you now, you're going to have to take  
22 a look at your witness lists, especially now with the sort of  
23 new issues coming to the fore. You're going to have to be  
24 selective on both sides. And keep that 18-hour limit, which  
25 covers your direct, your cross, your openings, your closings,

1 in mind. So that's one thing I want to tell you in advance.

2 Second of all, I don't know how much public interest -- I  
3 imagine there would be some in this case. Right now, the  
4 broadcast policies in our court and in the circuit are a little  
5 bit in a state of flux. Until I'm told otherwise, our current  
6 local rules do allow for broadcast of civil trials. But that  
7 may change. But I wanted to see if anybody -- if that doesn't  
8 change, and the Ninth Circuit doesn't direct otherwise, I want  
9 to see if there's any objection to putting this on Zoom.

10 **MR. CANNON:** No objection from Natera, Your Honor.

11 **MR. PERLOFF:** No objection here. And perhaps we can  
12 revisit the question of what documents are going to remain  
13 under seal if not only is it going to be public, but maybe even  
14 broadcast. We can visit that, perhaps, with them, after this  
15 call. But we'd like to look at -- look into that.

16 **THE COURT:** Yeah. Why don't -- why don't you all --  
17 I'd like you to meet and confer about that. Because it becomes  
18 an intractable problem -- although, of course, this will be a  
19 public trial, so whatever you do in terms of documents that you  
20 don't want to disclose publicly, that's sort of true whether  
21 it's broadcast or not. My understanding sensitivity --

22 **MR. PERLOFF:** Yeah.

23 **THE COURT:** -- broadcast magnifies that issue.

24 But I'd like you to meet and confer. And if there are  
25 some very substantial problems, and it's going to get in the

1 way of this trial, then I may reconsider the broadcast. But it  
2 seems to me in a case of public interest and transparency,  
3 Counsel is in favor of broadcast, but I will -- I'm certainly  
4 open to revisiting that.

5 **MR. CANNON:** Agreed.

6 **MR. PERLOFF:** Okay.

7 **MR. CANNON:** Agreed and understood, Your Honor. Thank  
8 you.

9 **THE COURT:** Okay. And in my pretrial conference  
10 report, I'll also set forth some procedural rules. Generally,  
11 I require the party to give the opposing party a 48 -- 48 sort  
12 of court hours' notice of witnesses it intends to call,  
13 exhibits it intends to seek to admit, and any demonstratives.  
14 The opposing party will have until the next day to indicate any  
15 objection. If it can't be resolved, I need to know about that  
16 the day before so that we can talk about it first thing in the  
17 morning the day of trial.

18 So there's kind of a two-day lead time. So keep that in  
19 mind that disclosures -- instead of one day ahead, I find that  
20 two days works, because it gives time for the objection, it  
21 gives time for me to look at it in advance, and my goal is to  
22 not spend any of the jurors' time kind of waiting around and  
23 listening to argument on admissibility.

24 And that would also apply to demonstratives for  
25 openings -- I want those disclosed in advance -- as well as

1 closings. I don't want to have objections to have to be ruled  
2 on in the middle of somebody's opening statement or closing  
3 argument. So I'd like that process to work, as well.

4 What I want to do is -- since we have a number of in  
5 limine motions -- I think something like 13 or 12 -- I want to  
6 go through some of those. Because some of those will also shed  
7 light on the evidentiary objections, as well. So why I don't I  
8 just start and talk about -- we'll start with Guardant's  
9 motions.

10 Motion Number 1 is to exclude attacks and criticisms of  
11 the Parikh Study. And I think part of what is sought to be  
12 excluded are some internal documents discussing this study;  
13 some evidence regarding the consequences -- alleged  
14 consequences -- of the study not being blind, which, as I  
15 understand it, it arguably informs the one-year cutoff date;  
16 and then some additional mischaracterizations about the  
17 landmark time of the draw and some other matters.

18 So to take their first issue of sort of these internal  
19 documents that -- as I understand, these are Guardant documents  
20 discussing the Parikh Study and whether there may be some  
21 issues there. It seems to me that Guardant's state of mind may  
22 be relevant, and, therefore, it seems like these documents  
23 would be admissible. But I'll hear argument on that.

24 **MR. PERLOFF:** Well, I think that our motion was  
25 focused as much on Natera's apparent intention to have their

1 expert witnesses testify on matters that you had actually  
2 excluded them on already.

3 So, you know, certainly if a document is discussing one of  
4 the areas that you've left in the case with respect to their  
5 counterclaim -- for example, the subject matter of blinding --  
6 when, you know, their clinical data was submitted, when it was  
7 sent, as well as whether or not the design was prospective or  
8 not -- then certainly that -- that would be relevant -- and  
9 relevant to state of mind, even if it was an internal document.

10 But, for example, I'm -- and I'm not sure that I have a  
11 particular document in mind that might be focused on one of the  
12 areas, for example, the cutoff time -- right? -- which -- the  
13 one-year cutoff time. That -- I'm not sure how that would be  
14 relevant to anything that was left in, insofar as the Court has  
15 already thrown out that issue.

16 **THE COURT:** Okay. Let's -- yeah. Let's talk about  
17 that one, because that's an interesting one.

18 **MR. PERLOFF:** Yeah.

19 **THE COURT:** Yes. I've not allowed that as -- if  
20 there's a critique about the methodology, using that cutoff,  
21 et cetera, et cetera, that is a -- I'll call it an ONY problem.  
22 And I will reiterate -- I know that Natera essentially wants to  
23 sort of reopen that discussion. And the jury instructions also  
24 talk about, you know, you can attack the reliability to the  
25 study and all that. But I'm not revisiting that. My views are

1 as I've stated.

2       But the one-year cutoff -- I understand there's an  
3 argument there that that is one of the consequences, or at  
4 least alleged consequences, of the non-blinding or unblinding  
5 of the study. I think, as I understand Natera's argument, that  
6 there was some retrospective quarterbacking here in choosing  
7 that date, or choosing that date post-unblinding, in order to  
8 achieve a certain result.

9       If that's the allegation, then it's not so much critiquing  
10 the scientific methodology of it, but it goes to the question  
11 of, you know, was there blindness or not, because there's a  
12 dispute as to what that really means. But if it meant one  
13 definition is -- once -- something of consequence occurred  
14 after unblinding, and, therefore, that's what blinding is  
15 about, then it does seem to me that there is an argument that  
16 it becomes relevant in that regard.

17       So maybe, Mr. Perloff, you can respond to that argument.

18       **MR. PERLOFF:** Well, I think part of this also is --  
19 you know -- so the question of blinding presumably has to be  
20 related to some of the advertising. And this has actually been  
21 an issue that we haven't quite been able to figure out from the  
22 rulings yet, which, you know, none of Guardant's advertising  
23 that they attack uses the term "blinded."

24       The description of the ctDNA analysis was conducted  
25 blinded. That's the statement. It was in the Parikh Study

1 itself, not in --

2                   **THE COURT:** And I thought that was the -- that was the  
3 challenge. That was the ONLY exception. That is, if the Parikh  
4 Study representative was blinded, and, in fact, it wasn't, that  
5 was the one door I left open under that narrow ONLY exception;  
6 that, and the prospective debate about whether the study's  
7 characterization itself was misleading or false.

8                   **MR. PERLOFF:** Right. And I guess what I'm saying is  
9 presumably you would still need to have some use of that  
10 statement unblinded as part of your -- as part of your  
11 advertising. And that -- that didn't occur. In other words,  
12 the ads that are at issue -- the Guardant ads -- don't say "in  
13 this blinded study" or "Parikh was blinded." The Parikh Study  
14 definitely does, but the advertising statements that they've  
15 attacked -- 91 percent surveillance sensitivity and 100 percent  
16 specificity -- those -- those don't say anything about  
17 blinding.

18                   **THE COURT:** Well, that's not my understanding of the  
19 theory -- the limited theory -- that the ad has then referenced  
20 what the falsity -- alleged falsity -- in the study was. If  
21 the study itself is unreliable because of some false  
22 representation or misleading representation about what -- how  
23 it was conducted -- then, you know, it kind of taints  
24 everything about the study and the reliance.

25                   And I think there's a theory that if you can attack the

1 study under the narrow exception -- not just generally, but  
2 under the narrow exception allowed by ONY -- that's fair game,  
3 even if it wasn't -- regardless of whether it was in an ad or  
4 not, since the study was relied upon for -- a lot.

5 **MR. PERLOFF:** Okay. So I guess if what you're saying  
6 is -- and this -- perhaps this -- if the issue of blinding --  
7 if they're able to tie it to -- and I think you even used this  
8 term -- a consequence -- right? -- that it informed the  
9 results -- so if they have a document -- if we're talking about  
10 a document -- that ties the issue of being unblinded to, for  
11 example, a specific statement like "100 percent specificity,"  
12 then I guess that it could be relevant and admissible.

13 But I guess part of my -- again, I'm not sure that I know  
14 which document they're focused on. And the reason -- because,  
15 for example, the Parikh Study reported both the results of  
16 specificity with and without the cutoff. You know, they showed  
17 all of the data and calculated it both ways.

18 So I'm having some trouble, I guess, seeing how they could  
19 do the connection. And I'm concerned that without having a  
20 bridge in advance -- if they're just going to be essentially  
21 rearguing the same point -- that that one-year cutoff was  
22 arbitrary -- because that was their argument -- that it was an  
23 arbitrary cutoff. They weren't attempting to tie it to  
24 blindness or prospectiveness.

25 **THE COURT:** Okay. Well --

1                   **MR. PERLOFF:** And then -- so that's -- do you see --

2                   **THE COURT:** Yeah.

3                   **MR. PERLOFF:** I'm concerned if we're going to use any  
4 sort of narrow opening to drive a great wedge and just simply  
5 reargue all of their criticisms of Parikh.

6                   **THE COURT:** In other words, there needs to be some  
7 foundation that ties the blindness discussion -- or --  
8 discussion with this particular decision about the one-year  
9 cutoff.

10                  **MR. PERLOFF:** I would think so. Because, again,  
11 otherwise you end up exactly back where we were before the  
12 summary judgment with them making attacks on the underlying  
13 methodology. Because, fundamentally, that decision, like the  
14 decision in how to conduct the surveillance analysis, was a  
15 methodological one that you correctly pointed out was  
16 accurately described in the study. So, yes, I --

17                  **THE COURT:** All right.

18                  **MR. PERLOFF:** -- would think that there has to be some  
19 tie.

20                  **THE COURT:** Okay. Let me hear from Natera.

21                  First of all, do I have your argument correct? And, if  
22 so, what is the foundational evidence that suggests the  
23 blindness question had anything to do with the choice of the  
24 one-year cutoff?

25                  **MR. BRAMHALL:** Sure. Sure, Your Honor. Andrew

1 Bramhall for Natera.

2 So let me just step back for a moment, Your Honor. We  
3 have two theories of establishment. And we discussed this in  
4 our brief. We have a theory about lack of support, whereby  
5 there are claims made by Guardant, in its advertising, that  
6 have no support in any study; reliable, fraudulent, fabricated,  
7 or otherwise. That is not what we're talking about here.

8 We're talking about the lack of reliability side of the  
9 coin, where Your Honor rightly pointed out -- Your Honor is  
10 applying ONY. We see it differently, but we understand that  
11 that's what Your Honor is doing. And there's an exception  
12 where, if the data is fraudulent or fabricated, then it can be  
13 the basis for a lack of reliability claim under Southland Sod.  
14 That's as we understand it.

15 **THE COURT:** Right.

16 **MR. BRAMHALL:** So we're talking about the second  
17 bucket here.

18 **THE COURT:** Yep.

19 **MR. BRAMHALL:** Under the second bucket, the blinding  
20 and prospective issues that Your Honor permitted to go  
21 forward -- those are, at their heart, methodological issues.  
22 So we don't agree with Counsel on the other side that  
23 methodological challenges to the study are off the table.

24 At the very heart of the study are the claims that it was  
25 blinded to ctDNA analysis and also it was performed as a

1 prospective study. The word "retrospective" never appears.

2 Now, we can talk about an example here with the one-year  
3 cutoff that was applied. The one-year cutoff that was  
4 applied -- we're not, Your Honor, going to violate your Daubert  
5 or summary judgment order. We are not going to argue how the  
6 study could be improved, optimized, or clarified. We're not  
7 doing that. We're not arguing that it's arbitrary.

8 What we're saying, Your Honor, for example, with the  
9 one-year cutoff, is that that decision was made unblinded and  
10 retrospectively, which are -- neither -- neither of those  
11 things are disclosed in the study. And, in fact, the study  
12 suggests the exact opposite was done. And this affects how the  
13 scientific community would evaluate the Parikh Study.

14 And what Mr. Perloff is right about is their -- their  
15 advertisement does not say the Parikh Study was a blinded and  
16 prospective study. But it does, Your Honor, rely on the Parikh  
17 Study for every one of its claims. And inherent to those  
18 arguments -- excuse me -- those marketing claims -- are the  
19 statements in the Parikh Study that it was both blinded and  
20 prospective, which we know are false based on the --

21 **THE COURT:** Well, that's -- that's my question. Now,  
22 I understand the argument that I thought I had --

23 **MR. BRAMHALL:** Sorry.

24 **THE COURT:** -- accurately summarized. My question  
25 is -- and what I think Mr. Perloff is saying -- is there some

1 foundational evidence that this is true? That this was a  
2 retrospective rigging of the -- you know -- choosing the  
3 one-year cutoff in order to get better results after it was  
4 unblinded?

5 **MR. BRAMHALL:** So, Your Honor, from a better results  
6 side of things, we understand. That's not what we're saying.  
7 But what we are saying is it was -- those decisions were  
8 prospectively -- excuse me -- retrospectively made unblinded.  
9 And there's ample evidence of that. It's in the summary  
10 judgment motion. We cited more of that, Your Honor, in our MIL  
11 opposition. There is ample evidence that these decisions were  
12 being made, including about the surveillance analysis, the  
13 one-year cutoff. They were all made after the fact. Putting  
14 aside the motivation -- sorry -- and it's not just documents,  
15 to be clear. There's deposition testimony.

16 **THE COURT:** But -- but was there any evidence -- yes,  
17 it was made timing-wise -- these decisions made after the fact.  
18 But the question was did the unblinding then inform the  
19 decision to go one way or the other to --

20 **MR. BRAMHALL:** 100 percent, Your Honor. Because they  
21 had, for example, 69 percent sensitivity right up until the  
22 point where they were about to submit the paper to the journal.  
23 And then Guardant came up with, retrospectively, a new  
24 definition to create a new analysis to change the results. And  
25 that's one of numerous decisions that were made after the fact.

1       And, frankly, Your Honor, the evidence does show those  
2 decisions were made to change the results so different results  
3 could be reported and then ultimately relied upon by Guardant  
4 in its advertising. We have ample documentation of that.  
5 There's no question.

6           **THE COURT:** All right.

7           **MR. BRAMHALL:** And it will come out at trial, Your  
8 Honor.

9           **THE COURT:** So, essentially, that -- I hate to use a  
10 derogatory word -- but manipulation or choice of criteria, for  
11 instance, to enhance the numbers, or make it look better, was  
12 made after unblinding and with full knowledge, retrospectively,  
13 how you could improve at least the appearance of results.

14           **MR. BRAMHALL:** For example, Your Honor, the  
15 surveillance analysis was only patients who recurred. You can  
16 only pick patients who recurred if you know the outcomes, if  
17 you're making retrospective decisions. So, again, that's just  
18 one example, Your Honor. And, again, there are many more. I'm  
19 not -- I know we have limited time and a lot of issues to  
20 discuss. But, absolutely, those decisions were made to  
21 influence the outcome.

22           And the problem is, Your Honor, had that all been  
23 disclosed in a very clear way, and the study said we did this  
24 unblinded, and we did this in a retrospective fashion, that  
25 might be a different story. But what we have is the study

1 tells the world it was both prospective and blinded when it  
2 wasn't. That's fraudulent. And Guardant knew and, frankly,  
3 the Parikh Study authors knew that these decisions were being  
4 made, to a large extent.

5 **MR. PERLOFF:** If I can respond?

6 **THE COURT:** Yeah, briefly. Then I need to move on.

7 **MR. PERLOFF:** Yeah. A couple of -- you notice that he  
8 completely sidestepped the question, utterly, of the one-year  
9 cutoff. And that's because they -- the testimony they took,  
10 the documents they have, clearly showed that the one-year  
11 cutoff was selected by the study authors -- not MGH --  
12 Harvard -- and not by us. And both sets of data --

13 **MR. BRAMHALL:** I --

14 **MR. PERLOFF:** Both sets of data had been reported to  
15 the public. So this idea that it could have been  
16 manipulated -- it wasn't. And there is no connection. On the  
17 surveillance analysis, again, the only thing they're saying is  
18 that temporarily -- temporarily -- that Guardant had the  
19 clinical data before that analysis was done. But they still  
20 have to connect it to the decision. And they haven't been able  
21 to do that.

22 And there is no evidence of that, because it's not true.  
23 And the reason why -- and this is the fundamental flaw in their  
24 analysis to begin with -- what this Parikh Study actually says  
25 is that the ctDNA analysis was performed blinded to the

1 clinical data. And that's because nobody would say the entire  
2 study was blinded when the study authors, by definition, had to  
3 know the data.

4 It was a very specific thing that was said. And this was  
5 where we got, Your Honor, in the summary judgment, to your  
6 conclusion and correct observation that the only evidence at  
7 all that they ended up putting forth, that showed -- that they  
8 tried to put forward -- showing a connection between unblinding  
9 and a change in the ctDNA analysis was that -- the QC caller --  
10 the Methyl95. And, at the end of the day, they had no evidence  
11 that the Parikh samples were used to create or inform the  
12 Methyl95.

13 And so, again, what I'm concerned about is them using just  
14 the temporal timing to, you know, create this very broad  
15 opening to do a side attack -- a blindside attack -- on Parikh.  
16 I don't think that --

17 **THE COURT:** Well -- okay. So this discussion  
18 demonstrates, I think, the very simple point that whatever you  
19 call it -- whether you call it blinding, unblinding, et cetera,  
20 et cetera -- what's key is whether it was consequential.

21 **MR. PERLOFF:** Correct.

22 **THE COURT:** Whether that unblinding was used in a way  
23 to manipulate, to put in crude terms, the results -- enhanced  
24 results -- et cetera, et cetera. And I guess it will boil down  
25 to, you know, whether there is evidence of that. Because if

1 there's no evidence of that nexus, then the choice of one year  
2 versus something else -- then that's just a straight-up  
3 arbitrary methodological attack, not a fraud attack.

4 So I don't know until I guess --

5 **MR. PERLOFF:** Right.

6 **THE COURT:** I mean, so far, you know, the evidence  
7 seems a little thin. But I will say that sort of the  
8 consequences -- the choices that were made that still have to  
9 be attacked now by Natera -- you know, there's an ONY line that  
10 I intend to adhere to. And if there's going to be a sort of  
11 fraud exception, there has to be a nexus. And whether I get a  
12 proffer of evidence at some point at a hearing with a jury, or  
13 something, but that -- I think that's going to be the approach  
14 that I will take.

15 **MR. PERLOFF:** And I think that's fair. If I might  
16 say, you know, there was an opportunity for them to proffer  
17 that evidence, because we attacked this directly in summary  
18 judgment. And that's why I referred to your observation that,  
19 after all of the statements that they made in Court about what  
20 the evidence showed, when it came time to put that evidence on  
21 the record, it boiled down to that one Methyl195 caller. And  
22 even you, you know, observed that it wasn't even clear for  
23 that -- you know -- you left open the door that they might be  
24 able to prove that.

25 **THE COURT:** Right.

1                   **MR. PERLOFF:** So -- and I guess what I'm concerned  
2 about is sort of the timing. But if there's a proffer and  
3 their claim that they'll be able to, outside of the jury, put  
4 on evidence, for example, from Parikh or Corcoran -- and they  
5 had their opportunity do to that -- but I didn't see it in the  
6 transcript -- and I was there -- that they were influenced or  
7 made those decisions. That would be one thing. I don't think  
8 they'll have it. But I do think the approach of making them  
9 show that the connection is vital.

10                  **MR. BRAMHALL:** Your Honor, we fully intend to show the  
11 nexus at trial. Obviously, we can't put all our evidence in  
12 the motions that we've filed so far. There is ample evidence.  
13 And I'll say, I completely disagree with Mr. Perloff about  
14 where the cutoff came from. We have documents talking about  
15 publication strategies to exclude false positives. That's  
16 somebody caught red-handed, Your Honor. So I won't go into  
17 this more. I think this debate shows --

18                  **THE COURT:** Okay.

19                  **MR. BRAMHALL:** -- that, at trial, there's going to be  
20 a disputed issue about this. And we'll put our evidence  
21 forward, and they'll put their evidence forward, and they can  
22 move for Rule 50 if they think it's appropriate.

23                  **THE COURT:** All right. Let me ask --

24                  **MR. PERLOFF:** That's what summary judgment was for.

25                  **THE COURT:** Well, let me ask about -- is there an

1 argument that there was a mischaracterization within the Parikh  
2 Study not only about prospectiveness and blindness, but about  
3 the landmark point of the draws of one month versus six months  
4 or something?

5 **MR. BRAMHALL:** Absolutely, Your Honor.

6 So there are three categories. I was going to get into  
7 this. There's the category of the claim -- the false claim --  
8 that the study is blinded when it was unblinded to ctDNA  
9 analysis. There's the false claim of it being prospective when  
10 it was retrospective. Then there's a third category under the  
11 ONY exception that Your Honor is applying that says where  
12 there's inaccurate descriptions of the methodology, that's an  
13 issue for ONY.

14 And, in fact, Your Honor said, whether the Parikh Study  
15 reported, quote, "artificially inflated clinical performance  
16 metrics is outside the purview of this Court so long as the  
17 methodology was accurately disclosed." And there are  
18 absolutely issues. So on the landmark, Your Honor, the study  
19 says it was approximately four weeks or approximately one  
20 month. But, in fact, what we discovered, through discovery,  
21 through deposing the witnesses, through the documents, is that  
22 it was not only four weeks, but it went all the way up to six  
23 months.

24 It was -- there were 78-day, 80-day, 90-day, 100-day,  
25 almost 200-day draws that were included in that landmark

1 definition. And that's a scenario where Guardant is not  
2 applying the definition that it actually put forth in the  
3 study. That's a classic inaccurate description, Your Honor.  
4 And there's more, but that is one that we talked about in our  
5 briefing.

6 **THE COURT:** All right.

7 **MR. PERLOFF:** Right.

8 **THE COURT:** Any response?

9 **MR. PERLOFF:** And was rejected.

10 I mean, I just want to point out that -- that was one of  
11 the ones that the Court specifically rejected, because, as the  
12 Court correctly pointed out, all of those data were there.

13 **MR. BRAMHALL:** But, Your Honor, that doesn't make the  
14 definition accurate. The definition -- so you got a lie on the  
15 one hand, and you got some truth on the other, but you still  
16 have the lie, Your Honor.

17 **MR. PERLOFF:** That's very trite. But the point was  
18 the Court specifically addressed this very question about  
19 whether the descriptions of the methodology were accurately  
20 described by Parikh at all. The Court concluded they were,  
21 and, for that reason --

22 **THE COURT:** So remind me --

23 **MR. PERLOFF:** -- dismissed.

24 **THE COURT:** -- did I expressly address the landmark  
25 representation? I can't remember now. I'd have to look back.

1 I'm not sure we -- I know I had focused in on prospective and  
2 the blindness. I don't remember there being much discussion  
3 about this particular blindness. If I already ruled on this  
4 expressly, then --

5 **MR. BRAMHALL:** Your Honor --

6 **THE COURT:** -- somebody's going to have to convince me  
7 that I was wrong. But if I didn't then --

8 **MR. BRAMHALL:** Sure. Your Honor --

9 **MR. PERLOFF:** I know that it was -- I know that it was  
10 explicitly briefed, as Mr. Bramhall correctly notes. And,  
11 again, the point that we made is for the very same reasons  
12 that -- the data were all there for the readers to be able to  
13 understand every single patient that was used in the study  
14 exactly when their time points were done.

15 **MR. BRAMHALL:** And, Your Honor, we asked the --  
16 Dr. Parikh about this. And she said it would take her hours to  
17 figure out which patients are on which analysis. So the fact  
18 that the data is buried somewhere in the study, but then the  
19 definition -- where the reader is going to review the text and  
20 try to figure out what's being done here -- that is absolutely  
21 incorrect.

22 And there's no denying that a six-month draw is not  
23 approximately four weeks or approximately one month from  
24 therapy. I just -- I don't see where we can get to a point  
25 where that's an accurate description that survives -- that

1 doesn't fall within that --

2           **THE COURT:** I will have to review my order again. I  
3 don't -- it doesn't ring a bell, to tell you the truth. I read  
4 it, but I have to go back. If I've ruled on this, and the  
5 parties had their chance to put up their evidence, and I've  
6 ruled and -- I've ruled. On the other hand, if this was one  
7 that was left untouched, I'd have to look at it and see.

8 All right. Let's go to the second -- the second --

9           **MR. PERLOFF:** Yeah, hang on.

10 Okay.

11           **THE COURT:** Okay. So the peer review comments --  
12 again, generally, if there's peer review comments that they  
13 tried to use to detract from the Parikh Study or its general  
14 methodology, that falls within the ONY situation; however, if  
15 there's something -- some comments -- about the doors are left  
16 open -- this, you know, critique about blindness when it really  
17 wasn't blind or prospectiveness may be the issue of -- with  
18 respect to the landmark time. But to an extent there's  
19 something there -- I'm not sure there is -- that peer review  
20 commented on the very issues that I found may fall under the  
21 ONY exception -- those would seem to be relevant.

22           So first question is, is there such evidence or are these  
23 general critiques -- I haven't read through all of the --  
24 there's a lot of pages there -- but you can tell me, is  
25 there -- are there things that are specific to the ONY

1 exceptions?

2 **MR. PERLOFF:** No. The -- so there's two buckets.  
3 There are the letters from the journals that it not publish.  
4 And those, you know, are generally talking about the size of  
5 the study and the fact that it isn't as novel anymore, because  
6 there had been other things published.

7 The internal critiques by the peer reviewers -- by  
8 definition, those were done before publication and were  
9 addressed by the publication to the satisfaction of those peer  
10 reviewers and the journal.

11 So -- and if you look, actually, at the documents, they're  
12 not talking about this question of -- they're definitely not  
13 talking about blinded. I don't think they're talking about  
14 prospective collection, which is what the actual terminology  
15 is, or the landmark draw. They're talking about other things  
16 that were then addressed by Drs. Parikh and Corcoran, to the  
17 satisfaction of everybody involved.

18 So it's -- is just an attempt to make it look like it was  
19 a shoddy study.

20 **MR. BRAMHALL:** Your Honor --

21 **THE COURT:** And is this what's embodied in TX-755, or  
22 are there other documents?

23 That's one of the bellwethers.

24 **MR. PERLOFF:** Yeah. I can -- and this was on -- I can  
25 put it up on the screen if it helps everybody.

1                   **THE COURT:** Sure. Yeah.

2                   It looks like either reviewer comments -- Reviewer  
3 Number 1, Arvind Dasari, for instance.

4                   **MR. PERLOFF:** This is 7 --

5                   **THE COURT:** 55.

6                   **MR. PERLOFF:** Yes.

7                   **THE COURT:** Yeah. Is that what you're referring to as  
8 the "reviewer comments"?

9                   **MR. PERLOFF:** Yes. And there are a few that look like  
10 this.

11                  **THE COURT:** There are others?

12                  **MR. PERLOFF:** There were three peer reviewers. And I  
13 think each of them said at least something. Some said more  
14 than others. And I want to just make sure that I'm reading  
15 this correctly.

16                  Is -- oh, help me here, guys. Is this one of the peer  
17 reviews?

18                  **MR. BRAMHALL:** So, if I may, I think it is. I think  
19 this is from the CCR publication. If you look at the top left,  
20 it says CCR-21.

21                  **THE COURT:** Yes.

22                  **MR. BRAMHALL:** So, Your Honor, this is peer review  
23 comments from the paper that ultimately published the study.

24                  **THE COURT:** Yeah.

25                  **MR. BRAMHALL:** But, importantly, there were multiple

1 journals that rejected the study before it was submitted to CCR  
2 where one of the authors is a senior editor. Those prior  
3 comments -- and maybe Mr. Perloff is not speaking about  
4 those -- those absolutely address the prospective,  
5 retrospective element.

6 I would encourage Your Honor to look at Exhibit KK, which  
7 is GHI00007967 to dash 70. That is one of the exhibits that we  
8 submitted. It is Journal of Clinical Oncology comments that  
9 were shared with one of the Parikh Study coauthors at Guardant.  
10 It absolutely raises -- in fact, I believe it has major  
11 comments from a peer reviewer -- this same issue that we've  
12 been talking about.

13 THE COURT: All right. So assuming there are --

14 MR. PERLOFF: I don't have --

15 THE COURT: -- comments from -- in the context of  
16 other potential journals that did pinpoint maybe the issue of  
17 prospectiveness, why isn't that relevant?

18 MR. BRAMHALL: I'm assuming you're not asking me --

19 THE COURT: I'm asking Mr. Perloff.

20 MR. BRAMHALL: -- because I think it is relevant.

21 THE COURT: I know you think it's relevant. I'm  
22 asking Mr. Perloff.

23 MR. PERLOFF: Oh, I thought you -- I apologize. I  
24 thought that you were asking --

25 THE COURT: No, no. I know -- I know your opponent's

1 position. I want yours.

2                   **MR. PERLOFF:** Well, you know, I think that we run into  
3 the problem -- so, if you remember, they had an expert witness  
4 who purports to testify about what the meaning is. We were  
5 able to take that witness' deposition and learn that her  
6 definition of "prospective" and "retrospective" is maybe more  
7 fluid -- and that's a generous way to put it -- than they would  
8 have us believe. Because, again, the actual statement in the  
9 study is not "the entire study is prospective." It's, you  
10 know, "the samples were collected prospectively."

11                  And so what we would lack, then, is the ability to go to  
12 this third party, A, to prove it up that that's what they meant  
13 and, B, to cross-examine them on it.

14                  **THE COURT:** All right. Well, then you're bringing up  
15 really a hearsay problem. Because that's the issue here, is  
16 this is essentially a hearsay from -- statement -- from a third  
17 party to another journal that allegedly is critical, but you  
18 have no opportunity to cross-examine hearsay.

19                  **MR. PERLOFF:** Right. And it's not clear to me, also,  
20 whether, for example, the criticism that he's referring to --  
21 because I don't have the document in front of me -- is making  
22 the connection that they would need to make here, which is that  
23 they're criticizing the description of a prospectively  
24 collected cohort -- you know -- that somehow being inaccurate.

25                  **MR. BRAMHALL:** Your Honor --

1                   **MR. PERLOFF:** So, again, just the general subject  
2 matter of -- because that may have been exactly the reason why,  
3 in the study, it says what it says and doesn't say, "This is a  
4 prospective study." It says --

5                   **THE COURT:** Well --

6                   **MR. PERLOFF:** -- "The samples were collected  
7 prospectively."

8                   **THE COURT:** That's right. So the issue is not whether  
9 the methodology is good or bad or correct in the way that it  
10 was -- blindness or prospectiveness -- was handled. It's  
11 really whether or not the study inaccurately characterized  
12 itself. So I would have to look at that -- whatever those  
13 critiques are. That wouldn't submit as a bellwether, I see, I  
14 don't think. I don't see it in 17 bellwether. But, in any  
15 event -- so one question is, you know, is it on point? But the  
16 other question is hearsay; what about the hearsay problem?

17                  **MR. BRAMHALL:** So, Your Honor, it is absolutely on  
18 point. For example, when Your Honor takes a look at it, there  
19 are statements about excluding patients a priori. That's a  
20 reference to the cutoff we were talking about earlier and the  
21 decision to exclude just the two patients who could be false  
22 positives. So that document I cited earlier refers to that --

23                  **THE COURT:** Okay.

24                  **MR. BRAMHALL:** -- as well as the overall retrospective  
25 nature of the study.

1       From a hearsay perspective, Your Honor, there's, one,  
2 this -- is -- goes to an issue Your Honor raised earlier, which  
3 is state of mind. This shows Guardant was aware of these  
4 comments in the process of drafting and editing the paper and  
5 chose to make no changes. So it goes to the fraud and the  
6 fabrication element of the study. It also goes to the state of  
7 mind of those in the field in terms of it wasn't just Natera  
8 that had these concerns about the study and the way it was run.

9       As Your Honor may recall, there's an argument by Guardant  
10 that Natera's actions were somehow improper in raising its  
11 concerns about the Parikh Study with third parties. This --  
12 these peer review comments by experts in the field go to show  
13 that that -- those actions were entirely legitimate. They were  
14 motivated by concerns that were shared by others. So there's a  
15 state of mind issue from that perspective, as well.

16       And then I'd say, in general, Your Honor, hearsay is about  
17 trustworthiness. There's no reason to believe these  
18 documents -- these peer review comments by luminaries in the  
19 field -- are anything but the most trustworthy documents. And  
20 they should at least come in, Your Honor, either as records of  
21 regularly conducted activity in the scientific publication  
22 context or under the residual exception of 807.

23       **MR. PERLOFF:** I'm fairly certain that there's actually  
24 case law that says that interim analyses like these wouldn't --  
25 do not meet the normal exception. But I also want to clarify

1 one major point. Unless somebody tells me I'm wrong, Guardant  
2 never got these. Guardant was not privy to the -- these were  
3 directed to Dr. Corcoran and Dr. Parikh, who had to answer  
4 them.

5 And if -- somebody on my team, if I'm wrong about this,  
6 let me know. Because I'm 100 percent certain -- and you can  
7 tell by the Bates number -- these came from the journal. And,  
8 for the record, they had an opportunity to take the deposition  
9 of the CCR Journal. They subpoenaed them, but they elected not  
10 to in order to prove them up. But Guardant -- and Dr. Grant is  
11 confirming I'm correct -- we never had these.

12 **MR. BRAMHALL:** Well --

13 **MR. PERLOFF:** Nor would we. This -- the study was  
14 conducted by -- written by -- Dr. Corcoran, Dr. Parikh. And I  
15 know they're trying to make our influence seem important. And  
16 we did have some editing. But not at this stage.

17 **THE COURT:** Well, okay. So that -- that creates a  
18 state of mind --

19 **MR. BRAMHALL:** But, Your Honor -- Your Honor, Victoria  
20 Raymond, a coauthor on the study, a Guardant employee, had  
21 these comments. If you look at the document I'm talking about,  
22 the very top email is an email from Dr. Corcoran to Dr. Parikh  
23 and Victoria Raymond of Guardant Health. This is the document  
24 I referred to earlier. These were absolutely shared with  
25 Guardant. It's Exhibit -- I believe -- is 46 the trial --

1                   **MR. PERLOFF:** Yeah, let me -- yeah -- if you give me  
2 that, I can see it.

3                   **MR. BRAMHALL:** I think -- and so I think it's -- is it  
4 TX-46 or something else?

5 It's GHI00007967. But I'm confirming the exhibit number.

6                   **MR. PERLOFF:** Yeah. If you give me the exhibit  
7 number, I can look and see what we're talking about.

8                   **MR. BRAMHALL:** Absolutely. So it's on the docket, as  
9 well, if you want to look at our Exhibit KK, but I'm working on  
10 this right now. It is TX-515.

11                  **MR. PERLOFF:** TX-515 -- if you give me a second...

12                  **MR. BRAMHALL:** And if you take a look at the -- and  
13 maybe Mr. Perloff was not aware of this -- but if you look at  
14 the "to" line of this email, at the top, it's to people from  
15 MGH. And it's Victoria Raymond at Guardant. And if you go  
16 down this email to the bottom, you'll see it's the Journal of  
17 Clinical Oncology comments. Now, they're a little funky  
18 because --

19                  **MR. PERLOFF:** Yeah. I -- I'm not seeing -- can you  
20 put it up on the screen?

21                  **MR. BRAMHALL:** I cannot at the moment.

22                  **THE COURT:** So what's the number? 515?

23                  **MR. PERLOFF:** I've got it.

24                  **MR. BRAMHALL:** Yeah. So assuming we're all looking at  
25 the same thing, which hopefully we are --

1                   **MS. SHYR:** Andrew, I'm able to share it if you'd like  
2 me to.

3                   **THE COURT:** Why don't you share it.

4                   **MR. BRAMHALL:** Yeah, if you could, that would be  
5 great. Just the top, since it's a confidential document. But  
6 you can show the top here -- well, you might have to scroll  
7 through to show the rest.

8                   But, yeah, this is -- this is -- if you look here, Your  
9 Honor, there's -- Dr. Parikh is the first. Victoria Raymond --  
10 and you see she has a [GuardantHealth.com](http://GuardantHealth.com) email address -- is  
11 second. And you see the subject is "JCO Final Decision."  
12 That's the rejection by the Journal of Clinical Oncology. And  
13 if you scroll down, it has commentary from the peer reviewers.  
14 There's a Reviewer 1 and a Reviewer 2. And Reviewer 1 is the  
15 reviewer who raised the comments I mentioned previously.

16                   So you look at point 2, "Was this decision to exclude them  
17 made a priori? This is a major decision to exclude those two  
18 patients as they would have been the only negative cases."

19                   If you go, Dr. Shyr, down to the minor comments, you see  
20 there's a comment about retrospective versus prospective.

21                   **MR. PERLOFF:** Hang on. Which number?

22                   **MR. BRAMHALL:** Point 2 in each, I think.

23                   **THE COURT:** Okay. Well, your main thinking is that  
24 this document, for hearsay purposes, went to [Guardant](http://Guardant.com) via  
25 Victoria Raymond. And so, if nothing else, this informs state

1 of mind.

2                   **MR. BRAMHALL:** Oh, yeah, and this one -- by the way, I  
3 should say, this is the version that was actually from  
4 Guardant's files. If you look at the bottom, it says "GHI" --  
5 there you go -- that's from Guardant's files.

6                   **MR. PERLOFF:** Okay.

7                   **MR. BRAMHALL:** Sorry.

8                   **THE COURT:** All right. Well, in sum, the -- any peer  
9 review sort of comments, number one, for relevance, would have  
10 to connect with the ONY exception and not just general  
11 critiques about sample size and this sort of thing. So that  
12 gets you into the relevance door. And then there's the hearsay  
13 door that's got to be passed.

14                  And I think the strongest argument I've heard so far is,  
15 to the extent that whatever documents you want to introduce  
16 went into the possession of somebody responsible at Guardant,  
17 it could be admissible as to Guardant's state of mind. The  
18 idea about state of mind in the field and Natera was --  
19 therefore their concerns were legitimate -- that -- that --  
20 that assumes the truth of the matter asserted. That's classic  
21 hearsay at that point.

22                  And I'm not so confident about residual hearsay. I'd have  
23 to think about that. But, right now, my take is that they may  
24 be relevant to state of mind. But if it's used to prove the  
25 truth of the matter asserted therein, i.e., there are problems,

1 et cetera, et cetera -- now, if it went to Natera, and Natera  
2 had possession of these before they decided to issue their  
3 campaign, et cetera, et cetera, you know, maybe I could see  
4 that. But I don't think that's the case here.

5 **MR. BRAMHALL:** Yeah. I'm not aware of that, to be  
6 clear, Your Honor.

7 **THE COURT:** Yeah. So I think if it's just generally  
8 here's the state of the field, I think there are -- you know --  
9 we don't know if it's -- how representative it is. There may  
10 be questions about what was meant by this, and what would cure  
11 this, and how consequential it is. That's what the value of  
12 cross-examination rights are and the problem with hearsay.

13 So I'll just say that there could be a serious hearsay  
14 problem there, but, again, this particular document does seem  
15 to be admissible, at least on the question of state of mind.

16 **MR. BRAMHALL:** And, Your Honor, we can understand your  
17 views on this, and we can take this up as we go at trial, and  
18 we will absolutely consider our evidence in light of your  
19 comments.

20 **THE COURT:** All right. What about the other  
21 studies -- this Motion Number 3 -- COSMOS, KASI, ECLIPSE?

22 **MR. PERLOFF:** Right. Yes. So --

23 **THE COURT:** So -- yeah. Go ahead.

24 **MR. PERLOFF:** Right. And, naturally, I actually think  
25 that COBRA would now fall into this category. Because it --

1 the description is the same. These are -- well, let me set  
2 aside ECLIPSE just for a second. ECLIPSE was about Guardant  
3 SHIELD --

4 **THE COURT:** Yeah.

5 **MR. PERLOFF:** -- which is the test that they're going  
6 to the FDA on.

7 **THE COURT:** Right.

8 **MR. PERLOFF:** It wasn't called SHIELD at the time, but  
9 that's what that was about. So difficult to understand the  
10 relevance of that to anything here. And I'm going to guess  
11 that they're not going to want to talk about ECLIPSE either  
12 because they're just about to go to final publication and the  
13 results were very favorable. So I'm guessing they may not want  
14 to bring ECLIPSE in, because the FDA is about to prove it based  
15 on ECLIPSE. But set that aside.

16 The COSMOS and COBRA -- both are interim analyses. Both  
17 are not peer-reviewed, published articles. And the same  
18 problems that we have for COBRA are the problems we have for  
19 COSMOS. For example, not necessarily all of the data has been  
20 reported out. Certainly, in COBRA, we don't have that.

21 And I think that -- our point is that -- and to echo,  
22 honestly, what Natera wrote in their matching motion to exclude  
23 other studies -- if you recall, they wrote it cannot be  
24 relevant to what Guardant advertised in 2021 what the results  
25 of an interim analysis were in 2022 or, in the case of COBRA,

1 late 2023.

2 And I believe that that's right. That the key issue that  
3 we're talking about here are specific claims -- you know -- so  
4 sensitivity, specificity, lead time -- that are in the  
5 advertising that they are attacking. And if those studies are  
6 interim, and we don't have clinical data to know what the  
7 sensitivity is or specificity is, because there's no, for  
8 example, reporting of the clinical outcomes, it can't be  
9 relevant.

10 And what we end up -- where we end up is going down these  
11 different little rabbit holes on these -- each of the  
12 individual studies. And there's, you know, an additional  
13 problem that presumably the studies are not going to have been  
14 as well-documented in terms of discovery; right? We're already  
15 talking about limiting the scope of our discovery on just one  
16 of the ones they want to bring in.

17 And it's especially true, given that the parties, in their  
18 discovery production to each other, made agreements about  
19 excluding documents that were only about these studies. And so  
20 I think that that's really the main point. The parties didn't  
21 seem, during discovery, to believe that they were relevant.  
22 And now they're trying to bring in, again, this interim data  
23 that was generated after the statements that -- advertising  
24 statements -- were made, and couldn't retrospectively have  
25 anything to do with the truth or falsity.

1                   **THE COURT:** Well, I'll hear the response, but, I  
2 guess, is that true? It has nothing to do with truth or  
3 falsity? I mean...

4                   **MR. PERLOFF:** Well, I guess that that -- I'm just  
5 borrowing their argument, that if it was good in --

6                   **THE COURT:** Yeah. Well, I know -- if it's good for  
7 the goose, it's good for the gander.

8                   **MR. PERLOFF:** Right.

9                   **THE COURT:** I saw that several times -- people talking  
10 about, oh, they deceive people. Oh, no, they weren't deceived  
11 by our advertising, because these were sophisticated doctors.  
12 I thought, oh, wait a minute, who's arguing what?

13                  But, in any event, what about -- what about -- I guess --  
14 this is the question -- this is something after the fact, after  
15 the ad. The attack is on the truthfulness of the ad -- the  
16 accuracy of the ad -- or the advertisement. Is it probative?  
17 Is the interim -- putting aside it's not final, there are  
18 issues about, you know, how reliable it is, et cetera,  
19 et cetera, how much weight you should give to it -- but  
20 assuming there's some evidence here that would tend to  
21 contradict the statements in the ad one or two years prior, is  
22 it relevant?

23                  **MR. PERLOFF:** Well --

24                  **MS. SHYR:** Your Honor, may I respond to that?

25                  **THE COURT:** Yeah.

1           **MR. PERLOFF:** Do you want me to go first or --

2           **MS. SHYR:** Thank you, Your Honor. So --

3           **THE COURT:** No. I was going to ask Ms. Shyr to  
4 respond and then you can.

5           **MS. SHYR:** Thank you, Your Honor.

6           So regarding the COSMOS Study that was in Guardant's MIL  
7 Number 3, that one has already been discussed in the Hochster  
8 Daubert motion. And, in that, it was found that COSMOS is  
9 relevant to whether Guardant's ads are false and -- because  
10 they have claimed that Reveal has 100 percent specificity.

11           Now, the data from COSMOS has shown that there's a high  
12 number of false positives, which relates to a corresponding low  
13 specificity for Reveal. So it's directly relevant to the  
14 falsity of Guardant's claims. Similarly, COBRA is relevant for  
15 that purpose. And, actually, I came into this hoping that the  
16 dispute about whether COSMOS came in had been mooted, because,  
17 on the February 15th hearing, Mr. Perloff referred to  
18 additional data from COSMOS that he was suggesting might be  
19 relevant to further discovery.

20           **THE COURT:** So, remind me, why is it -- if you could  
21 just say, in as few words as possible, why is it that something  
22 after the fact -- let's say a year or two later, a study  
23 reveals that the statement in an earlier ad does not appear to  
24 prove out correct. That -- that's relevant because it just  
25 tends to show the absolute truth, even if it's a year older, or

1 a year beyond, and therefore what was -- whether that statement  
2 a year earlier was inaccurate?

3 **MS. SHYR:** That's right, Your Honor. That Reveal does  
4 not have 100 percent specificity, because a public study showed  
5 that there was incidents of high -- of false positives -- which  
6 corresponds to low specificity.

7 **THE COURT:** Does it go to state of mind? If these  
8 studies weren't known, is there an argument for or against  
9 that -- whether it goes to the actual absolute truth or not, it  
10 does not inform state of mind, culpability, scienter?

11 **MS. SHYR:** With respect to COSMOS, Your Honor, yes, it  
12 does. Because there are internal Guardant documents showing  
13 that Guardant was aware of these false positives and encouraged  
14 the investigators to leave those out of the public reports.

15 **THE COURT:** Well, what about COBRA, now that we're on  
16 that subject? This is now two years later -- three years  
17 later. Are you arguing that COBRA also informs a question of  
18 Guardant's scienter?

19 **MS. SHYR:** Your Honor, we -- we don't have discovery  
20 about Guardant's -- what Guardant knew about COBRA. But I  
21 think COBRA, based on the incidents of false positives, further  
22 supports that Reveal does not, in fact, have 100 percent  
23 specificity --

24 **THE COURT:** All right.

25 **MS. SHYR:** -- to the absolute truth.

1                   **THE COURT:** So it goes to what's the absolute truth  
2 and whether what was stated back in whatever -- 2021 -- was, in  
3 fact, inaccurate.

4                   **MS. SHYR:** Yes, Your Honor.

5                   **THE COURT:** Okay.

6                   What's wrong with that, Mr. Perloff?

7                   **MR. PERLOFF:** Well, the statements that were made in  
8 2021 were based on the clinical validation study in 2021. And  
9 you correctly noted these data were not available in 2021 when  
10 Guardant made the statements that they're alleging are false.

11                  So if you think about a false advertising case, how could  
12 it be that -- when it was -- unless we do some type of time  
13 manipulation -- right? The -- there could always be data that  
14 comes along later that undermines data that occurred earlier.  
15 But it doesn't make the statement -- you know, when Guardant  
16 says 91 percent sensitivity in the surveillance setting and  
17 cites Parikh -- it doesn't make it false. Because it was.

18 That's the data that they're reporting on in the advertisement.

19                  **THE COURT:** So, in other words, if the statement under  
20 what some of you call the establishment claim -- I'm not sure  
21 where that nomenclature came from -- but if you use that --  
22 that prong -- that is there was -- your argument is that the  
23 statement was not untruthful back in 2021, because it was  
24 supported by the Parikh Study. Not criticizing the study, but  
25 if found it supported the study back then, then it's not false.

1 The fact that there's later studies that then tends to show  
2 that, no, actually it wasn't an accurate statement, that  
3 doesn't make the then-statement based on -- supported by data  
4 then -- unsupported.

5 **MR. PERLOFF:** Yes. That -- I think that's right. And  
6 it's particularly, I think, true when you are dealing with the  
7 ONLY situation with peer-reviewed, published studies.

8 And, again, just also, for the record, in neither case --  
9 neither COSMOS nor COBRA -- I -- for 100 percent certain, there  
10 are no clinical outcomes reported in COBRA. We do not know  
11 whether any of the calls were true positives, false positives,  
12 true negatives, false negatives, precisely because the clinical  
13 recurrence was never reported, at least to us and not to the  
14 study authors, as far as we know.

15 Same thing with COSMOS. The issue back in 2021 was they  
16 were still within a year of blood. And, you know, again, the  
17 idea is recurrence comes later.

18 And that's sort of the problem -- right? -- Your Honor.  
19 What they're trying to do is make something false. The Parikh  
20 Study was finished. They had the clinical data that they  
21 reported. In COSMOS, they're ongoing. So what they're saying  
22 today is a false positive could become a true positive  
23 tomorrow, because the patient recurs. That's the problem on  
24 top of what they're doing.

25 I still think the fundamental issue is you couldn't go

1 back in time and render it false by something that happens in  
2 the future. But for sure you can't do it when the future isn't  
3 set. When those have not been reported out so we know what the  
4 actual outcomes of those patients were. And we end up going  
5 down these rabbit holes to go through each one of these points  
6 for each one of these studies.

7                   **THE COURT:** All right. Let me ask -- go back to  
8 Ms. Shyr. If the question is, at the time a statement is made,  
9 whether it was, in fact, established -- i.e., supported by the  
10 study or did the statements go beyond and say something that  
11 the study didn't support -- that's the issue under the  
12 so-called establishment claim -- why does it make any  
13 difference what happened two years later? It either was  
14 supported back in 2021 -- or whenever the statements were  
15 made -- or it wasn't supported.

16                   **MS. SHYR:** Well, Your Honor, regarding the COSMOS  
17 Study, at least, one of the exhibits that Guardant attached to  
18 its motion in limine -- it's labeled Exhibit 87 in my printout.  
19 But this is an email that was sent to -- CCing someone at  
20 Guardant in September of 2021. That's before the Parikh Study  
21 was published.

22                   **MR. PERLOFF:** Your Honor, Parikh was published in  
23 March or April of 2021; right? The launch of Reveal was  
24 announced at JP Morgan in January. The actual launch -- soft  
25 launch -- occurred in February. The Parikh Study was

1 published, I believe, in April. And that's, of course, when  
2 this lawsuit began in May.

3 **MS. SHYR:** Well, the preprint was published in  
4 April --

5 **THE COURT:** So, anyway, what was --

6 **MS. SHYR:** -- and the article was published -- the  
7 preprint was published in April. The published version  
8 appeared in October of 2021.

9 **MR. PERLOFF:** Oh, the online -- it was published  
10 online. It just didn't make it into print until the September  
11 print version of the journal. But it was the final study.

12 **THE COURT:** Well, anyway, what's the relevance of this  
13 email?

14 **MS. SHYR:** Well, what I'm saying is at the time that  
15 Guardant was relying on these statements of 100 percent  
16 specificity, it was aware of these issues with false positives  
17 in COSMOS.

18 **THE COURT:** All right. So this is relevant because it  
19 was within the awareness of COSMOS at the time the advertising  
20 statements were made for COSMOS?

21 **MS. SHYR:** That is -- that's correct. Yes, Your  
22 Honor.

23 **THE COURT:** Okay. I think I understand that point.  
24 But now that we're on the subject of COBRA, what about that?  
25 That did not exist. So, I guess, it begs the question, what is

1 the relevance of something that's totally post hoc and not  
2 within the mindset or knowledge of Guardant? How is that  
3 relevant if the question under the establishment claim is  
4 whether or not the advertising statements by Guardant was, in  
5 fact, supported by the Parikh Study at the time?

6 **MS. SHYR:** I think that -- thank you, Your Honor.

7 So the point is that they weren't established by Parikh at  
8 the time. And Parikh, in its falsely reported methodology --  
9 for lack of a better term -- it did not allow physicians to  
10 understand that there were these false positives. So this was  
11 an issue, at the time, that was concealed by the conduct of the  
12 study by Guardant.

13 **THE COURT:** Well -- all right. I don't know if we're  
14 now talking about the study, and we're in the ONY land and the  
15 falseness of the study, or the falseness of the ads, which  
16 misrepresented the study, in a sense. But that still doesn't  
17 answer my question.

18 Yes, they -- you have an argument that it did  
19 misrepresent. They went further -- or they said something that  
20 wasn't supported by the study. That argument exists, they got  
21 a counterargument, et cetera, et cetera. My only question is  
22 why should we admit evidence of a three-year or two-year post  
23 hoc event that neither side was aware of at the time? How does  
24 that establish whether there was an accurate summation of the  
25 study back at the time in 2021?

1           **MS. SHYR:** And, Your Honor, I see that Mr. Cannon is  
2 at the podium. He addressed the COBRA Study. So if I could  
3 pass this over to him.

4           **THE COURT:** Okay. All right. All right. But it does  
5 seem like this Motion Number 3 kind of folds into COBRA a bit.

6           You're muted, Mr. Cannon.

7           **MR. CANNON:** There we go. Thanks. Sorry. I just  
8 wanted to jump in since I addressed the COBRA and Dr. Hochster  
9 issue earlier.

10          And one of the issues is -- and you raised a good point --  
11 is why is this -- why is it that the COBRA's termination --  
12 termination of the COBRA Study based on excessive false  
13 positives? How does that relate to advertisements that came  
14 before?

15          And the reason is, Your Honor, Guardant is accusing  
16 Natera -- the accusations against us is, hey, Natera, how can  
17 you question our ads? In fact, Guardant sued us for doing  
18 comparative advertising and questioning the ads, because,  
19 immediately, when Parikh was published, when the advertisements  
20 that Guardant put out there showed the sky-high specificity and  
21 very low false positives, Natera knew, based on the technical  
22 design of that product -- on Guardant's Reveal product -- there  
23 would be false positives. Natera suspected that.

24          Dr. Hochster, our expert, who was revealed and was  
25 disclosed to Guardant earlier on in his case, said that in his

1 first report, Your Honor. He said, hey, there's a much higher  
2 chance of false calls -- false positives -- based on the design  
3 of Reveal. And the COBRA Study is ongoing.

4 And, in fact, in Your Honor's Daubert decision -- that was  
5 from March 23rd, 2023 -- ECF Number 328 on page 11, Your  
6 Honor -- you actually ruled that Dr. Hochster could discuss  
7 this issue. And the opinion that Dr. Hochster said, which  
8 survived Daubert -- in your Daubert order -- you say, "Second,  
9 he opines that Reveal is more prone to false calls and can lead  
10 to negative, undesirable health consequences for patients."

11 So what that shows is Dr. Hochster, an oncologist,  
12 suspected, hey, the design of the Reveal test shows a lot of --  
13 you know -- potentially a lot of false positives -- way more  
14 than the Parikh Study and the Guardant advertisements are  
15 telling the field. And, lo and behold, the COBRA Study  
16 vindicated his opinion that was set forth in his opening  
17 report. So that is how --

18 **THE COURT:** So that's your key. The "lo and behold"  
19 nexus. Even though he opined at the time that the -- that  
20 what -- I mean, justifying Natera's critiques --

21 **MR. CANNON:** Right. So Natera critiqued the Guardant  
22 ads. Guardant sued Natera based on those critiques. And  
23 Dr. Hochster had an opinion that the technical design of the  
24 Reveal test could lead to more false positives. That was an  
25 opinion he put into the case.

1 There was Daubert motions about it. Your Honor issued an  
2 order. And the COBRA test, which was identified in his  
3 original report -- and it was a Guardant Reveal test used in  
4 the COBRA test -- turned out to have excessive false positives,  
5 exactly as Dr. Hochster said would happen. And so that is the  
6 relevance of that. Natera is defending itself against  
7 Guardant's accusations, and that's the relevance there.

8 **THE COURT:** Well, so what you're essentially arguing  
9 is that Dr. Hochster's prognostications or concerns have now  
10 proven correct and therefore -- is that the idea? -- and  
11 therefore Natera's express concerns and attempt to bring those  
12 concerns to light to the public back in 2021 were justified?

13 **MR. CANNON:** That's a big part of it, Your Honor.  
14 Guardant is suing Natera for critiquing Guardant's product and  
15 for critiquing the very high performance metrics that Guardant  
16 advertised that Reveal had. And so the COBRA test and the very  
17 dramatic termination of the COBRA test is an important -- very  
18 important relevant piece of evidence -- a relevant piece of  
19 evidence that confirms an already existing opinion in the case.  
20 And the already existing opinion is Dr. Hochster's opinion that  
21 Reveal is more prone to false calls; in other words, false  
22 positives.

23 **THE COURT:** All right.

24 Mr. Perloff?

25 **MR. PERLOFF:** There's a huge problem in Mr. Cannon's

1 analysis. And that's simply that none of the criticisms that  
2 are the subject of our false advertising claims against them  
3 say the word "specificity" at all. They know that.

4 This is -- this is -- they're trying to do a sideline  
5 around here. If you remember the comparison, none of the  
6 comparisons said anything about specificity. So they're just  
7 trying to juke and jive here.

8 The Hochster issue -- so -- and you raise it -- it's the  
9 lo and behold problem. So Hochster, relying on COSMOS in 2022,  
10 said that he believes that the statement made in 2021 about  
11 specificity was false. It doesn't say anything about COBRA.  
12 But perhaps equally important, you'll notice that Dr. Hochster  
13 didn't supplement with the most recent COSMOS data. Because,  
14 again, part of our argument is, when it's not a closed trial,  
15 and the studies are ongoing, you don't really know what the  
16 clinical truth is, whether true positive or false positive.

17 And, certainly, again, in the case of COBRA, nearly three  
18 years later, wasn't known, couldn't have been known, and  
19 doesn't render what was said in 2021, true or false, doesn't  
20 render citing from Parikh, true or false. It can't.

21 **MR. CANNON:** Your Honor, if I may respond, briefly?

22 **THE COURT:** Yeah.

23 **MR. CANNON:** The opinion -- Dr. Hochster's original  
24 opinion -- is relevant, and it is in the case, per your Daubert  
25 order, on page 11. The fact that Dr. Hochster had the opinion

1 that Reveal -- the Reveal technical design -- leads to more  
2 false positives, that is an opinion that's in the case.

3 And with respect to the accusations that Guardant has  
4 against Natera, I very much believe that the accusation is in  
5 the case. Because Natera did critique the specificity, you  
6 know, of the Reveal -- the Reveal product.

7 I'm looking at Exhibit 68, which has been put in front of  
8 me. And it was certainly my understanding, before looking at  
9 this exhibit, that Guardant's -- that Natera's -- critique of  
10 the Guardant product, in particular with respect to false  
11 positives and specificity, was part of the advertisements and  
12 the marketing that Guardant claims is false.

13 So if Guardant gets to accuse Natera of false advertising  
14 with respect to Natera's critiques of Guardant's products,  
15 Natera is entitled to defend itself by saying, hey, our  
16 critiques were on point.

17 **MR. PERLOFF:** But only if those critiques relate to  
18 this -- this is assuming that it's even true that -- your  
19 argument. But the statements -- the comparisons -- that we're  
20 talking about -- that began after the Parikh Study, after the  
21 launch of Reveal -- they do not talk about specificity. The  
22 Court will remember going through, in the summary judgment,  
23 each of the comparisons that we alleged were false. None of  
24 them have to deal with specificity. It's because Natera did  
25 not discuss specificity in its advertising after Parikh was

1 published, at all.

2 **MR. CANNON:** Well, I'm looking at Exhibit 68, which is  
3 a Natera marketing piece.

4 **THE COURT:** Why don't you -- why don't you put that on  
5 the screen.

6 **MR. CANNON:** Yeah. I don't have the ability,  
7 unfortunately, to do that. If there's someone on the team that  
8 would do that, that would be great.

9 **MR. PERLOFF:** It is, Mr. Cannon, the one from 2019 or  
10 2020?

11 **MR. CANNON:** Well, it's Exhibit 68. And, you know, we  
12 can bring up -- we can bring up documents on the fly with the  
13 Court, obviously, and discuss them. But, to me, I go back to  
14 the Daubert order where this opinion about Reveal's -- that  
15 Reveal is prone to false positives -- Dr. Hochster's opinion --  
16 that, to me, shows this opinion or this issue is very much in  
17 the case in terms of Natera defending itself.

18 **MR. PERLOFF:** Right.

19 **THE COURT:** Well, it may be, if that's what was part  
20 of the advertising here.

21 **MR. CANNON:** So if we can scroll to the second -- top  
22 of the second page -- top right corner -- "Specificity is  
23 impacted" -- so the issue here is, Your Honor -- as you may  
24 recall the technical nature of this --

25 **MR. PERLOFF:** Right.

1                   **MR. CANNON:** -- Natera's test is what's called  
2 tumor-informed, which means you take a little piece of the  
3 tumor and actually get a genetic fingerprint for each  
4 individual patient, which makes it, you know, very, very  
5 accurate, whereas the Reveal -- Guardant's Reveal test -- is  
6 what's called tumor-naive, where you don't actually take tumor  
7 tissue to make kind of a BESPOKE test. You just test the DNA  
8 in the blood draw. So -- so that's -- you know -- this is one  
9 of the ads, I believe, that's been accused of -- subject to --  
10 subject to --

11                   **MR. PERLOFF:** Right.

12                   **MR. CANNON:** -- subject to accusation. And there's a  
13 critique of the specificity based upon noise from germline and  
14 CHIP mutations. And, in fact, Your Honor, in your -- in the  
15 summary judgment ruling -- which is ECF 326, on page 26 --  
16 there is a discussion of the CHIP filter. CHIP has to do with  
17 mutations in the blood that may get picked up by some of these  
18 tests because --

19                   **THE COURT:** I understand that's an issue.

20                   **MR. CANNON:** -- we filter that out. Yeah.

21                   So -- so our white paper claims that our device -- that  
22 Signatera device -- I'm reading from the -- I'm reading from  
23 the MSJ ruling -- you know -- it's our position -- it's  
24 Natera's position -- that the Signatera design significantly  
25 reduces false positive rates by filtering out some of these

1 artifacts -- these sort of noncancerous DNAs.

2 And so it's the -- this is a very important part of  
3 Natera's product and Natera's advertising claims. And the fact  
4 that Natera promotes its specificity and critiques Guardant's  
5 specificity -- that's an important part of the case. That's in  
6 the case from the summary judgment motion, from the Daubert  
7 ruling, and Natera should be able to defend its advertising.

8 You know, it's -- our advertising is being accused of  
9 being false -- falsely misleading -- and we ought to be able to  
10 defend it. And this evidence goes right to the heart of that,  
11 Your Honor.

12 **MR. PERLOFF:** Well, if I may, very quickly.

13 **THE COURT:** Briefly, and then I've got another  
14 question.

15 **MR. PERLOFF:** Yeah. It's the -- the actual  
16 statement -- and I know they're pulling it down, because maybe  
17 they're hoping you didn't see it. But the whole point is that  
18 statement was the very specific statement that we did attack,  
19 that specificity is allegedly impacted by the lack of a CHIP  
20 filter, which we established we do have a CHIP filter. They  
21 knew we had a CHIP filter. It's not a generalized statement  
22 about we have better specificity or Guardant Reveal has poor.

23 And just the last point, the fact that you allowed  
24 Dr. Hochster's opinion about COSMOS --

25 Thank you for putting that up. I appreciate it.

1       It's impacted by biological noise from germline and CHIP  
2 mutations. And without being able to suss that out, you would  
3 have the problem. That's -- that is a specific attack. We  
4 have criticized that. But that's because it wasn't true. We  
5 do have a chip filter.

6       But the other point about Dr. Hochster -- the fact that  
7 you allowed him to testify about COSMOS is not letting him  
8 necessarily talk about COBRA. They are two different things,  
9 both in timing and, again, also even whether or not there are  
10 any clinical data reported. So I don't think they've ever  
11 answered your question.

12       **THE COURT:** All right. Let me ask you one last  
13 question in that regard. Is -- is something like COBRA not  
14 relevant to damages? To the extent that you're going to have  
15 to demonstrate -- if you prove liability, prove loss of  
16 income -- what's going to be required to correctively, you  
17 know, fix the problem, et cetera, et cetera, if, in fact,  
18 that -- it's proven as a matter of fact, even after the fact --  
19 that there are problems with -- with the assay? Why wouldn't  
20 that inform damages?

21       **MR. PERLOFF:** Well, our damages for lost sales only go  
22 through May of 2022. So something reported in November of  
23 2023, or at ASCO in January of 2024, couldn't. We -- both  
24 parties have not exchanged damages information. And our  
25 damages number comes from what happened in -- only through --

1 launch through May of 2022. So that's --

2 **THE COURT:** You're not seeking prospective loss sales?

3 **MR. PERLOFF:** It's not even just prospective. We  
4 haven't sought damages after -- lost sales damages -- after May  
5 of 2022, at all.

6 Now, that may be a subject, but we haven't -- they haven't  
7 offered to update their sales figures. And so I'm not exactly  
8 sure how it could possibly inform that. It couldn't. It's  
9 closed; right? That same universe of time is closed.

10 Something that happens in 2023 couldn't impact what happened in  
11 2022.

12 And as far as something like corrective advertising, the  
13 corrective advertising we're going to seek to do has to do with  
14 the claims that they made, again, which were not about  
15 specificity. In other words, the fact that they may -- that  
16 doctors may or may not have an issue because of COBRA doesn't  
17 change the market that they created when they badmouthed us  
18 about everything but specificity in 2021. In other words, we  
19 would still have to go and correct those false ads.

20 It may very well be that separate from that, we may have  
21 to go to the world and explain to them that, no, there were not  
22 false positives in this case. They drew the blood during  
23 chemo, or whatever, and then, you know, muzzled the primary  
24 investigator from talking about it. But that's a separate  
25 issue from the amount of money that we would need to correct

1 what they did say, which, again, wasn't anything about a lack  
2 of specificity.

3 **THE COURT:** All right. Comment -- response -- to the  
4 damages -- why damages are not -- any claim for damages for  
5 prospective relief is not --

6 **MR. CANNON:** Well, yes, Your Honor. I mean, the  
7 specific damages theories are a little bit outside of my  
8 agreement on this -- on this call today. But I will say that  
9 the consumers who are actually looking at these tests are  
10 oncologists who are very sophisticated consumers. And a lot of  
11 this technical information is -- I don't want to say "baked  
12 into decision-making" -- but the -- sort of the risk or the  
13 thought or the concern of false positives is based on this  
14 technical design you would think would be a causal factor in  
15 terms of some of the sales.

16 So to have a lost sales -- a lost sales claim -- in this  
17 case, and completely say, well, the false positives issues  
18 can't be a causal factor, when, certainly, false positives was  
19 on the radar of a lot of technical folks in this field, I think  
20 is unfair. I think COBRA does bear upon damages in that  
21 regard, only to the -- at least to the extent it undermines a  
22 lost sales theory. Because a lost sales theory posits that  
23 Guardant's allegedly false advertising somehow took sales away  
24 from Guardant. And we know, from the COBRA results, that may  
25 not be the case. There may be other factors at play that these

1 physicians were considering.

2                   **THE COURT:** Well, that would be obvious if they're  
3 seeking prospective loss sales. But I'm being told that  
4 they're cutting off their claim for lost profits, lost sales,  
5 as of May 2022, before COBRA. So you've got to look at the  
6 state of the world and the what-if world, you know, back then,  
7 before COBRA. So I'm not sure how, after the fact, it sort of  
8 changed the understanding of the public, et cetera, et cetera,  
9 back in 2022.

10                  **MR. CANNON:** Well, I hear you, Your Honor. I don't  
11 have -- I don't have the facts in front -- at my fingertips --  
12 to know the exact date of that damages cutoff. But the idea  
13 that a tumor -- a tumor-naive test -- would have the chance for  
14 higher false positives than a tumor-informed test -- that would  
15 have been in people's buying decisions from the very beginning;  
16 right? That's --

17                  **THE COURT:** And you can certainly argue that, and I'm  
18 sure you will.

19                  **MR. CANNON:** And that will be in argument, you know,  
20 so -- and then COBRA would sort of vindicate that concern for  
21 at least some cohort of the potential consumers of these tests.  
22 But I don't -- I don't have the numbers in front of me to know  
23 exactly when the damages cut off to confirm or deny that  
24 statement.

25                  **THE COURT:** All right. Well, that's something I need

1 to think about, because now these motions in limine have sort  
2 of raised to the forefront this whole question about sort of  
3 after-the-fact studies. I think those that were within the  
4 mindset of Guardant and within the knowledge, there's a fairly  
5 good argument -- or at least a stronger hook -- that they would  
6 be in play. Those which were not, and sort of longer after the  
7 fact -- upon reflection, I need to think about that a little  
8 bit here.

9                   **MR. PERLOFF:** Your Honor --

10                  **MR. CANNON:** I will say, Your Honor, that Guardant was  
11 involved in the COBRA Study. So it was the Guardant Reveal  
12 test that was used. And, you know, we don't have discovery  
13 from the sponsor of the study, but we do know that Guardant was  
14 involved.

15                  In fact, Mr. Perloff seems to have indicated some inside  
16 information about alleged pressure on principal investigators  
17 and their reasons for the termination. That's information I  
18 don't have and Natera doesn't have, but apparently Mr. Perloff  
19 and Guardant do. So Guardant was involved in the COBRA test.

20                  **MR. SCOLNICK:** Your Honor, can I make one quick point?  
21 It's 30 seconds. I think it's very important to this -- to  
22 this issue.

23                  And, one, with respect to the allegations of false  
24 positives, there's no evidence that any of these tests are  
25 false positives, because there's no clinical data.

1       Second -- and this undercuts, apparently, Natera's entire  
2 theory of admissibility -- is that there's nothing  
3 inconsistent. Assuming they were false positives, if you have  
4 six or seven false positives out of a set of 600 people, that's  
5 99 percent specificity.

6       In fact, we put this in front of the Court. In our  
7 motion, there is a slide from our presentation -- that Parikh  
8 Study -- the Parikh ASCO presentation -- that shows, with 1,000  
9 people, and a test that has 50 percent sensitivity at landmark,  
10 which is what we're dealing at -- and with these tests  
11 generally -- both of them -- if you have a test with 98 percent  
12 specificity, you would expect 18 false positives. That's with  
13 98 percent specificity.

14       Here, we have 600 people, not 1,000. So doing the math,  
15 we'd expect, with 98 percent specificity, to have 11 false  
16 positives. Now, again, we're -- our contention is that no  
17 false positives occurred here. But even giving them the  
18 benefit of the doubt, if we have six, that's about 99 percent  
19 specificity. There was --

20       **THE COURT:** Well, there's a lot of assumptions --

21       **MR. CANNON:** Well, Your Honor --

22       **THE COURT:** There's a lot of assumptions there about  
23 what the base was and how many people were tested and all that.  
24 We don't have enough -- I don't have enough yet to know --

25       **MR. CANNON:** Your Honor, can I please -- I know that

1 it was a quick 30-second or a one-minute -- I would love to be  
2 able to just quickly respond to that, because there was a lot  
3 of numbers and assumptions baked into that math.

4 **THE COURT:** Well, and I understand. I just said --

5 **MR. CANNON:** Yeah.

6 **THE COURT:** -- I understood that's based on a lot of  
7 assumptions --

8 **MR. CANNON:** Yeah. And I would say that -- I mean,  
9 you know, all due respect to Mr. Scolnick -- but the NRG  
10 Oncology sent a letter -- and I don't have it electronically --  
11 but it was in Dr. Hochster's supplemental report. And NRG  
12 Oncology certainly said, quote, "The higher than expected false  
13 positive rate resulted in the trial not passing the interim  
14 analysis."

15 **THE COURT:** Yeah. Well, I think --

16 **MR. CANNON:** So the experts in the field pointed to  
17 that as the reason for COBRA ending.

18 **THE COURT:** Well, I think there's a bigger threshold  
19 question, and that is relevance here, which I need to think  
20 about.

21 **MR. PERLOFF:** Your Honor --

22 **THE COURT:** Let's go to Number 4.

23 **MR. PERLOFF:** Oh.

24 **THE COURT:** We're going to move on to Number 4.

25 **MR. PERLOFF:** All right. Thanks, Your Honor.

1                   **THE COURT:** The motion to exclude lay witness  
2 opinions -- I'm not sure what it is that's being sought to be  
3 introduced here. I mean, to the extent that Mr. Chapman and  
4 Dr. Aleshin -- is it the idea that they would speak about their  
5 understanding of the terms used in Guardant's advertisement,  
6 and that, therefore, informs the state of mind of Natera? Is  
7 that the basic argument here, or what is it?

8                   **MS. LOZANO:** Your Honor, this is Valerie Lozano for  
9 Natera. This is Guardant's motion, and I'm a little bit with  
10 you that I don't know exactly what the scope is of what's  
11 trying to be excluded. It's quite broad in a way --

12                   **THE COURT:** Well, maybe you can start by telling me  
13 what's trying to be included on your part. Something like  
14 that.

15                   **MS. LOZANO:** I mean, you know, we don't intend to have  
16 our witnesses speculate about other people's thought processes  
17 or motivations. But, for example, I do think it's potentially  
18 very relevant that they testify about their understanding of  
19 what's important to the customers of their products, which goes  
20 to their state of mind about why they put what they did in  
21 their responsive ads to correct the misimpression in the  
22 marketplace. So I think that's absolutely an example of  
23 something that's relevant.

24                   **THE COURT:** So it's relevant to Natera's state of  
25 mind --

1 MS. LOZANO: Right.

2 THE COURT: -- to show that they had a genuine  
3 concern --

4 MS. LOZANO: Right.

5 MS. KELLER: Your Honor, if I could be heard.

6 We did lay out, in our motion, exactly what we wanted to  
7 exclude. We wanted to exclude their testimony of these lay  
8 witnesses; of how oncologists and other physicians understand  
9 and interpret Guardant and Natera's advertising; what other  
10 physicians believe about tumor-informed and plasma-only ctDNA  
11 tests; the factors that are most important to physicians in  
12 choosing MRD assay for their patients; the beliefs,  
13 understandings, motivations, and intentions of Guardant and  
14 other third parties; whether Guardant Reveal met the criteria  
15 for Medicare coverage; how Guardant has achieved Reveal's test  
16 performance. Okay? We were very specific.

17 So I was quite pleased to see, in Natera's response, that  
18 they said, hey, we're not going to get into any of that. None  
19 of those categories are on our witness list. And we're not  
20 going to ask anybody to opine about those.

21 Then they turned right around and said but, you know, they  
22 can opine about those, and we can simply object at trial.  
23 They -- they appear to be saying you can preface any improper  
24 lay opinion by saying that you either believe or don't believe  
25 something, or it's your understanding, and that somehow

1 immunizes the statements from admissibility, because they're,  
2 quote, "personal opinions." That was what they said.

3 That's pretty tautological. And it would really  
4 obliterate the distinction between 701 and 702. And if you  
5 look at the cases that they cited to support their position,  
6 they cited two Northern District cases -- unpublished decisions  
7 of district courts ruling on motions in limine. They were both  
8 criminal cases.

9 One was a criminal case involving a computer intrusion.  
10 And Judge Orrick ruled that employees who discovered the  
11 intrusion -- that assessed it and repaired it -- could testify  
12 to what they did without running afoul of 701, because they're  
13 fact witnesses, even if this involved some technical issues,  
14 because they dealt with them every day. So they weren't giving  
15 opinion testimony.

16 And U.S. v. Chen was also a criminal case. It involved  
17 trade secrets. Judge Freeman ruled that she was not going to  
18 exclude testimony of applied materials employees as experts,  
19 because they were just going to testify that certain technical  
20 information was treated as confidential; how they stored CAD  
21 drawings or bills and material in a secure, confidential  
22 database; and how --

23 **THE COURT:** Okay. No, I -- Ms. Keller, I understand  
24 the distinction between 701 and 702. My question is -- that's  
25 why I'm trying to get at exactly what is the testimony that is

1 sought. If it's sought to elicit why -- if they had a role --  
2 a percipient role -- in saying here's how we formulated the  
3 ad -- the letters to, you know, various oncologists -- because  
4 we were concerned with blah, blah, blah -- X -- and this was,  
5 you know, a term that -- you know -- that we thought was  
6 confusing, that's one thing.

7 To opine about how oncologists in the field -- when  
8 interpreted -- what -- the reaction of doctors, generally --  
9 that does, to me, sound like 702 territory. So --

10 **MS. KELLER:** Exactly.

11 **THE COURT:** -- it's unclear to me. But if -- if they  
12 say I was involved in designing the letter that went out -- the  
13 ad -- et cetera -- part of the campaign -- part of our concerns  
14 were based on X, Y, and Z -- that -- although that would  
15 involve some opinion, because it involves some degree of  
16 explaining how they interpreted the ads and the statements made  
17 by Guardant -- that would be more of a 701 type.

18 **MS. KELLER:** It really sounds, though, like they're  
19 getting into 702 territory on page 3, where they say, "Given  
20 their tenure positions at Natera, they both have interactions  
21 with oncologists and physicians regularly and, thus, have  
22 personal knowledge about the performance metrics of MRD assay,  
23 such as the meaning of specificity and sensitivity and what  
24 oncologists believe is important to an MRD test." And it goes  
25 on from there. And it --

1                   **THE COURT:** Right. So let me hear --

2                   **MS. KELLER:** I understand --

3                   **THE COURT:** Let me hear from the proponents of this  
4 testimony. That's why I asked, what is it that's being sought  
5 to be introduced here?

6                   **MS. LOZANO:** So, again, Your Honor, you know, I think  
7 this goes back to where I started, which is our witnesses --  
8 and I -- you know -- I think they're, you know, attempting to  
9 call them all adversely. So I don't quite know what questions  
10 they're going to ask and what [sic] they're going to open the  
11 door. There is proper lay opinion testimony. And, certainly,  
12 these witnesses can testify about their understanding of what  
13 is important to these products and how that impacted their --

14                   **THE COURT:** What is important to whom?

15                   **MS. LOZANO:** Important to the people purchasing it.  
16 And so how that impacted their concerns when they saw  
17 Guardant's ads, and whether they thought they were material and  
18 problematic and needing of correcting or not, and why they put  
19 out the ads that they did. And I don't see how we can agree  
20 to -- their brief asks the evidence to be excluded -- you  
21 know -- unreliable, irrelevant, speculative, inflammatory  
22 opinion testimony, including Natera's beliefs, understandings,  
23 actions.

24                   Like, this should be dealt with at trial on a  
25 question-to-question basis. And if it becomes clear that

1 there's some pattern of improper testimony, you know, maybe  
2 there is -- there is a time --

3                   **THE COURT:** So what will be the foundational evidence  
4 about Mr. Chapman and Dr. Aleshin's role in the -- I'll call it  
5 the campaign -- the anti-Guardant campaign?

6                   **MS. LOZANO:** They were all intimately involved in it.  
7 There's ample evidence about that, I think. I forget the name  
8 of the -- the name that they used to describe their meetings  
9 that they had and how they decided what ads to put out to  
10 direct the misimpressions. But Mr. Chapman was intimately  
11 involved with that.

12                  **THE COURT:** So, Ms. Keller, why -- if they were  
13 involved -- and they certainly could testify as a percipient  
14 witness what they did, what they saw, how the ad came to be,  
15 since that's a central part of the case. Why can't they  
16 explain why they did, since their state of mind, their  
17 culpability, their scienter -- and that of Natera -- is at  
18 stake, why can't they explain what went through their mind, and  
19 why they thought this information was going to be absorbed by  
20 the market, and was going to have consequence, et cetera,  
21 et cetera?

22                  **MS. KELLER:** They can testify to that, Your Honor.  
23 We're not saying they can't. What they can't do is go way far  
24 afield from that and start to give general testimony. From my  
25 understanding -- you know -- you have somebody like Chapman

1 who's not a scientist. He's not a doctor. He's a business  
2 guy. He's got a bachelor's in -- you know -- in a science  
3 degree. But, you know, he starts to go into sensitivity for  
4 longitudinal tracking and surveillance and all sorts of other  
5 categories; whether he thinks something is confusing; whether  
6 he thinks that, you know, it's misleading for us to portray  
7 91 percent sensitivity, and as longitudinal sensitivity, and  
8 juxtapose that. He starts to go into areas -- deep -- into  
9 areas of expert testimony.

10 I can see if he wants to get up and say, look, I was told  
11 by the experts that they were presenting misleading  
12 information, and that it was misleading in a number of ways,  
13 and it was going to harm our product by comparison. And so we  
14 decided to launch this ad campaign. But when he starts to  
15 spout -- because it's not enough to just say "it was my  
16 understanding," and then spout a huge amount of what would  
17 otherwise be expert testimony. I think that's going too far.

18 **THE COURT:** Well --

19 **MS. KELLER:** But I understand -- I understand exactly  
20 what the Court's saying, and I agree with you.

21 **THE COURT:** The question of degree and the final  
22 analysis -- this always happens in a 701 situation -- at what  
23 point are you sort of going beyond immediate experience and  
24 giving testimony that is of the type that an expert would have  
25 to decide, based on their expertise, because 701 does contain a

1 limit. It does require that the opinion, quote, "not be based  
2 on scientific, technical, or other specialized knowledge within  
3 the scope of 702." So --

4 **MS. KELLER:** That's right. That's exactly right.

5 **THE COURT:** You know, it always involves something,  
6 whether it's the owner of the business talking about lost  
7 profits. There's going to be some expertise in there.

8 On the other hand -- so it is a question degree, and I'll  
9 be alerted to that. I think if it's tethered closely to what  
10 happened, and explaining the whys as it gets further out, and  
11 begins to look like relying on sort of expertise that's of a  
12 702 nature, somewhere there's a line out there. Whether we  
13 approach that, I don't know. But I'll just say that for now.

14 **MS. KELLER:** Okay. Thank you, Your Honor.

15 **THE COURT:** What about -- and the Medicare coverage  
16 question -- there's not a claim here that the information  
17 provided by Natera resulting in the delay of the Medicare  
18 coverage -- that's not an element of damages here; right?

19 **MR. SCOLNICK:** Your Honor --

20 **MS. KELLER:** Nor is it in within the expertise of  
21 either one of these witnesses.

22 **THE COURT:** Yeah. Well, so the stuff about criteria  
23 for Medicare -- it seems to me that's not relevant --

24 **MS. LOZANO:** Well, Your Honor --

25 **THE COURT:** -- since that whole Medicare approval

1 question is not an element of damages.

2 MS. LOZANO: Well, I --

3 MS. KELLER: And -- and I must -- and, Your Honor,  
4 Natera said, in their reply brief, they weren't going to ask  
5 about that category. That was one of the categories they said  
6 we're not going to even ask about it.

7 MS. LOZANO: Well, I think we're maybe speaking past  
8 each other. We actually have motions in limine about, you  
9 know, their attempts to say that the time it took for  
10 Medicare -- for Mo1DX to give them Medicare coverage -- was  
11 somehow Natera's fault. So we certainly think that should be  
12 out. If they're going to get to speculate about our  
13 conversations with Mo1DX being the reason that they were unable  
14 to get approval, I think our people need to be able to talk  
15 about the conversations they had --

16 THE COURT: Yeah. Well, I'll forecast this now. The  
17 stuff about the Medicare -- I don't see that as part of this  
18 case. That's not part of the damages theory.

19 MR. LAVIGNE: Your Honor --

20 THE COURT: If we got into that, that raises all sorts  
21 of difficult questions. We'll talk about that more when I  
22 get to --

23 MR. LAVIGNE: Your Honor --

24 MS. KELLER: Your Honor, before we -- before we --

25 MR. LAVIGNE: Your Honor, may I just jump in for a

1 second?

2 In terms of damages, Mr. Malackowski -- our damages  
3 expert -- he did not quantify, in real dollars and cents, what  
4 the loss was from the delay in Medicare reimbursement. But he  
5 essentially opines that this is unquantifiable.

6 And if Your Honor recalled, part of his report was he  
7 outlined what the degree for lost profits was, what the degree  
8 for disgorgement was, what the degree for corrective  
9 advertising was, and then said those numbers are conservative,  
10 given the fact that there's harm to Guardant's reputation and  
11 also harm to its goodwill.

12 And he specifically mentioned the delay in Medicare -- in  
13 Mo1DX approval -- as one of the factors. One of the reasons,  
14 based on the testimony in the case, is the industry perceives  
15 Mo1DX approval as basically an imprimatur for the product. And  
16 when that gets delayed, it can have very significant  
17 consequences.

18 So it's accurate to say it's not a specific dollar  
19 component of damages, but it is a component and a key theory of  
20 our case. I understand we can table this discussion until we  
21 argue on the Mo1DX motion in limine, but I do just want to flag  
22 that so the Court's aware of it.

23 **THE COURT:** All right.

24 **MS. KELLER:** Your Honor, there's a -- there's a big  
25 difference between our showing that they deliberately

1 interfered behind the scenes with us getting Medicare approval  
2 to try to salt our launch versus them being experts in what's  
3 required for Medicare approval; especially lay witnesses. So I  
4 don't think those two issues are identical. And we do intend  
5 to show that they deliberately tried to keep us from getting  
6 Medicare approval, behind the scenes, without any transparency.

7 **THE COURT:** Well --

8 **MS. LOZANO:** Your Honor, I think if they're going to  
9 argue that and be allowed to, then we should not be putting a  
10 gag order about what our witnesses can say in response and  
11 should deal with that at trial.

12 **THE COURT:** Well, I think the issue -- well, we should  
13 probably address the question of how much of this is coming in.  
14 But if it does, I think the argument is their expertise -- if  
15 they have an opinion -- you know -- it doesn't seem to me a  
16 701-type opinion to say whether the denial and delay of  
17 Medicare coverage was justified, et cetera, et cetera, in  
18 getting into what constitutes a permissible -- or what are the  
19 criteria for coverage.

20 **MS. KELLER:** Right.

21 **MS. LOZANO:** They're not going to speak to Mo1DX's  
22 ultimate conclusions or thought processes or why that criteria  
23 exists. But there is a basic background. They had Medicare  
24 approval through Mo1DX long before. They understood the  
25 criteria. And so that informed why they talked to Mo1DX, which

1       Guardant intends to paint them as, you know, bad actors for  
2       speaking to Mo1DX.

3           So I think -- again, we're probably putting the cart  
4       before the horse here since we haven't argued our MIL -- but,  
5       if that's coming in, I do think that they need to have leeway  
6       to explain what motivated them to reach out to Mo1DX. Because  
7       Guardant is going to paint that as a bad action.

8           **THE COURT:** All right. Let me -- let me skip through  
9       a couple of things. Let me just ask one on Number 6. And  
10       that's the deletion of emails in another case and then the  
11       allegations in the Illumina case.

12       With respect to the latter, theft -- alleged theft -- in  
13       and of itself was not necessarily reflective of dishonesty.  
14       But I take it here it's because the nature that this was --  
15       there was deceitful conduct in conjunction with the trade  
16       secrets appropriation. Is that the idea? That's why it goes  
17       to question of honesty under 608.

18           **MR. JOHNSON:** That's correct, Your Honor.

19           **THE COURT:** I'm not sure I understand the argument.

20           **MR. JOHNSON:** Yes. Kevin Johnson.

21       And, yes, Your Honor, that is correct. You know, we  
22       believe, again, this -- to the extent that the two founders are  
23       going to talk about -- and, you know, talk about truthfulness,  
24       and talk about reputation, and talk about -- and truthfulness  
25       obviously is a big part of this false advertisements case. And

1 they are going to be witnesses that are going to be front and  
2 center on the Guardant side.

3 And I'm not sure what the inventors are actually going to  
4 say on direct. You know? But the fact that they were found  
5 to have -- you know -- one of the founders was found to have  
6 destroyed documents after a deposition that occurred by a  
7 federal magistrate judge. And the fact that they were -- you  
8 know -- started a company and -- while they were still working  
9 for another company -- those are issues -- those are issues  
10 that are potentially fair game, for the reason Your Honor  
11 articulated.

12 **THE COURT:** All right. So it seems to me that the  
13 governing structure here is 608 of the Federal Rules of  
14 Evidence, which allows, if there's a good-faith basis to  
15 believe, questions on cross-examination. You don't have to --  
16 unlike 609 -- you don't have to have proof of a conviction or  
17 you don't have to have a judgment. A lot of times you -- none  
18 of this stuff even goes to court that you can ask about under  
19 608.

20 However, you cannot use extrinsic evidence to bolster  
21 that. So you have to ask. And as the commentators say, you  
22 have to accept the witness' response. If the witness, you  
23 know, denies, or whatever, that's it. But I see this as a  
24 608 --

25 **MR. JOHNSON:** Understood.

1                   **THE COURT:** I see this is a 608 question.

2                   **MR. LAVIGNE:** Your Honor, can I just respond to that,  
3 briefly?

4                   **THE COURT:** Yep.

5                   **MR. LAVIGNE:** It is a 608 question. They can  
6 introduce extrinsic evidence. They put a number of exhibits on  
7 their list that relate to this. But I want to provide the  
8 Court with some additional data. Because it's just false to  
9 state that Dr. Eltoukhy was found to have spoliated evidence.

10                  Ultimately, what happened -- and I can give the Court as  
11 much context as it wants -- Dr. Eltoukhy was in a situation  
12 where he was in a dispute with Foundation Medicine, FMI. In  
13 the context of that dispute, all of his documents were  
14 collected, including documents from his personal email and his  
15 personal computer.

16                  He was then shown those documents, some of which went back  
17 to 2014, at a deposition. The documents he was shown related  
18 to his prior employer, Illumina. After that, he realized he  
19 still had access to them. With the full understanding that  
20 everything had been backed up and saved by his employer --  
21 Guardant Health -- he deleted them. That then became an issue  
22 in the litigation.

23                  Guardant's Counsel confirmed and got his prior laptop, got  
24 his backup, and was able to produce all the materials. There  
25 was no spoliation, is the bottom line. Nothing was lost. Any

1 spoliation motions were withdrawn.

2 There was recently a trial that Guardant had -- the  
3 TwinStrand case -- in November 2023. This is one of the  
4 reasons why this trial got adjourned. And the judge in the  
5 District of Delaware was faced with this same issue. He did  
6 not allow introduction of this issue or any cross-examination  
7 on it.

8 After hearing from the parties, including Counsel from  
9 Guardant who represented Guardant in the Foundation Medicine  
10 case, that's because there was no spoliation. Dr. Eltoukhy was  
11 asked about this, extensively, at his deposition, for the  
12 better part of an hour. He testified consistently with what I  
13 just said.

14 He did not deny deleting those emails. He said he did so  
15 because he thought it was confidential information of Illumina.  
16 He realized he still had them, and he wanted, you know, it to  
17 be gone from his personal computer. And he understood that the  
18 company still had access to everything. So it doesn't bear on  
19 truthfulness, because there was no spoliation.

20 My concern, Your Honor, is when they start even asking a  
21 question about spoliation and destruction of evidence, even if  
22 my client gives a denial, we're going to have to rebut it. And  
23 we cited a couple of cases in our brief that outline this.  
24 When a witness, for example, has been acquitted of conduct, he  
25 should not then be permitted to ask and answer questions about

1 it on cross-examination, because it can leave the impression  
2 with the jury that he did something wrong. So that's why, on  
3 that, I don't think this should even be permitted on 608.

4 On this alleged trade secret misappropriation, that also  
5 is a complete red herring. There was a lawsuit filed. That  
6 case was ultimately settled. And if you actually read Natera's  
7 brief, they basically have issues with conduct that occurred 13  
8 years ago. That Dr. Eltoukhy and Dr. Talasaz started Guardant  
9 when they were still working at Illumina. Well, Dr. Eltoukhy  
10 was a paid consultant. Illumina was aware of Guardant. There  
11 have never been any adverse findings of trade secret  
12 misappropriations. So, for the same reasons, I don't believe  
13 this is appropriate under 608.

14 **THE COURT:** All right.

15 Brief response, Mr. Johnson?

16 **MR. JOHNSON:** Briefly, Your Honor.

17 This case, in large part, is about, you know,  
18 truthfulness. And their personal credibility will be front and  
19 center. The judge in the District of Delaware made a  
20 determination, you know, quote, "It is clear that  
21 Dr. Eltoukhy's deletion of these emails came after Dr. Eltoukhy  
22 was asked about the emails at a deposition."

23 You know, it goes to, ultimately -- you know -- again,  
24 it's going to be fodder, you know, potentially for  
25 cross-examination. And to the extent that the question is

1 asked, you know, he'll have an opportunity to explain what  
2 happened, and certainly on redirect.

3 And, frankly, you know, it all depends upon what they  
4 testify on direct as to what they're going to be crossed on.  
5 And -- but -- but, at least, at this point, you know, issuing a  
6 motion -- an order on a motion in limine -- when we don't even  
7 know what they going to say, I think, is putting the cart  
8 before the horse in large measure. And, you know, I think we  
9 understand what the issues are. And it depends on what they  
10 say. And we can take it up depending upon what their  
11 testimony --

12 **THE COURT:** Well, but what about -- what about  
13 Mr. LaVigne's argument that the doctor was essentially  
14 "acquitted," quote/unquote?

15 **MR. JOHNSON:** He was not acquitted, at all. He has  
16 not been acquitted. There is no -- there is nothing anywhere  
17 that acquitted him of any wrongdoing anywhere.

18 **THE COURT:** What about the judge's decision -- what  
19 I'm told -- in Delaware to exclude this evidence because there  
20 was no -- it wasn't sufficient evidence of spoliation?

21 **MR. JOHNSON:** Yeah. I mean, that -- Your Honor, that  
22 wasn't in their brief, as far as I'm aware. And I'm not sure  
23 what -- whether that -- what that case is, or what the facts  
24 are around that, and whether it's a false ads case or not.

25 This is a false ads case. Truthfulness is front and

1 center. And notwithstanding what a particular judge did in  
2 that case, we did cite what Judge Burke found with respect to  
3 the deletion of emails. That is part of this motion. I'm not  
4 sure what Mr. LaVigne is referring to right now.

5 **THE COURT:** All right.

6 Mr. LaVigne, is there some papers that haven't been filed  
7 with this Court that I should know about?

8 **MR. LAVIGNE:** Your Honor, this decision came out  
9 November 7th, 2023. It was after we filed our brief. It came  
10 to my attention, frankly, over the weekend, when I was  
11 preparing. It's an oral decision from the bench. District of  
12 Delaware Case Number 21-1126. And it's from Judge Gregory  
13 Williams. And he denied the application to explore this issue  
14 at the trial.

15 **THE COURT:** So what do I do about the magistrate judge  
16 finding?

17 **MR. LAVIGNE:** The magistrate judge finding -- what  
18 happened was the judge made that finding -- the judge had  
19 ordered discovery. During the course of that discovery, it was  
20 clear that Guardant had all of Dr. Eltoukhy's emails. And the  
21 spoliation motion was withdrawn, and the case ultimately  
22 settled. So there was no --

23 **THE COURT:** So the magistrate judge's ruling was not  
24 the last word, is what you're saying.

25 **MR. LAVIGNE:** Absolutely. There was going to be a

1 full-blown hearing on spoliation. Ultimately, that motion was  
2 withdrawn, and the case then settled.

3       But, you know, this bears on character for truthfulness.  
4 And what Dr. Eltoukhy testified at his deposition under oath,  
5 what he'll testify to on the stand, and what is true, is there  
6 was no subterfuge here. There was no attempt to do anything  
7 wrong. He deleted them because he didn't want to still have,  
8 in his possession, confidential --

9           **THE COURT:** All right. Do you have a transcript from  
10 the district judge's -- or the judge's -- vindication,  
11 quote/unquote, of Dr. Eltoukhy?

12           **MR. LAVIGNE:** I do.

13           **MR. JOHNSON:** I --

14           **THE COURT:** Well, I think you ought to share that with  
15 Counsel and the Court, because you're just citing something now  
16 that I haven't seen, that Counsel hasn't seen.

17           **MR. JOHNSON:** And, Your Honor, I will say, in this --  
18 in this case, we asked him about these emails in his  
19 deposition. And he -- he basically said he couldn't remember  
20 what happened, you know, when he was confronted with the  
21 Court's order during his deposition.

22           And so, again, this goes right to his credibility of  
23 whether he's to be believed or not, whether he's stating the  
24 truth. And that's the purpose behind this. And, again, it all  
25 depends upon what they have him say on direct as to whether

1 this will be used on cross-examination. But at least at this  
2 state of the game, we think it's fair -- it's fair game and  
3 fair use.

4 And to hear about -- I mean, you know, hear about  
5 something that occurred in November -- or, I guess, July of  
6 2023 -- now, you know, in the actual argument -- I mean, I just  
7 don't know what to say about that.

8 **MR. LAVIGNE:** Okay. Well, what you can say about it  
9 is the decision came down November 7th, 2023. This was after  
10 the brief was filed.

11 **THE COURT:** Well --

12 **MR. JOHNSON:** And, again --

13 **THE COURT:** I'll let you -- okay. That's enough. You  
14 submit whatever the transcript is. Give it to Counsel. Give  
15 it to the Court. Submit it in the next day. I'll look at it.

16 But I will state, my view is that Rule 608, unlike 609,  
17 has a pretty low basis. I understand there's a risk of  
18 prejudice. But it doesn't take proof to be able to ask  
19 somebody on cross.

20 Now, if somebody's actually been acquitted in a formal  
21 sense, you know, I can see an argument that then you no longer  
22 have a good-faith basis. But I'll have to look at what the  
23 judge said exactly and what I can glean from that.

24 So let's -- I want to move on to Natera's MILs. But we  
25 need to take a break. The court reporter's been going at it

1 for two hours now. But I do have a time limit. I have a hard  
2 stop at 5:15. So we may have to continue this to another date.  
3 I have time on Friday to continue this hearing, because I still  
4 want to get through these MIL's and a few other matters.

5 **MR. JOHNSON:** We're available on Friday, Your Honor.

6 **THE COURT:** All right. All right. So let's -- let's  
7 go ahead and take a ten-minute break and we'll resume.

8 **THE CLERK:** Court is in recess.

9 (Recess taken at 4:36 p.m.)

10 **THE CLERK:** Court is reconvened.

11 **THE COURT:** Okay. Let's address Natera's motions.

12 Number 1, essentially I read as seeking to reconsider the  
13 question about whether or not the ads could be false by  
14 necessary implication on the apples to oranges comparison. And  
15 I understand that many of the cases talk about different  
16 products, and these are similar products, et cetera, et cetera.

17 But I think that the general gist is if you -- whatever it  
18 is you're comparing -- tests, products, studies, stats -- I  
19 think the general principle, as I have stated, is if you're  
20 comparing things that truly aren't comparable, or you're  
21 leaving out the basis of a real difference that shows they're  
22 not really comparable, and leading the public to think they are  
23 comparable, that's -- that can be actionable. So my ruling  
24 stands. I'm not going to reconsider it. So any motion to  
25 reconsider that is denied.

1 Let's talk about the MolDX stuff now. This comes from --

2 **MR. CANNON:** Your Honor -- Your Honor, my -- Your  
3 Honor, I -- with all due respect, may I -- may I address that  
4 issue? And I'm very sensitive to revisiting a decision that  
5 Your Honor has made. I do think, with a full trial coming up  
6 on false advertising, this issue was not -- there's nuances to  
7 this issue and the false advertising rule, Your Honor. And I'd  
8 appreciate the chance to at least give you a very short pitch  
9 about why maybe we can --

10 **THE COURT:** I'll give you a one-minute pitch.

11 **MR. CANNON:** Okay. Thank you, Your Honor.

12 Your Honor, if we allow the doctrine of false by necessary  
13 implication to apply in all comparative cases, what we are  
14 doing is destroying the delineation between cases of falsity --  
15 literal falsity -- and misleading. Because there really is a  
16 significant difference in the case law. Because if something  
17 is literally false, then a lot of presumptions flow from that.  
18 There is no need to prove actual deception. Misleading -- if  
19 something is misleading -- right? -- it's not literally false,  
20 but it's misleading -- then, there, you have to prove  
21 deception. And, here, what we have is an accusation of  
22 misleading; right? That the data from the study was --

23 **THE COURT:** Why the difference between products and  
24 tests?

25 **MR. CANNON:** Well, the case law --

1                   **THE COURT:** Your argument is that, oh, these cases are  
2 different because they involve products involving one --

3                   **MR. CANNON:** Yes. That is part of the argument. Yes.

4                   **THE COURT:** Why draw the line there? What's the  
5 logic?

6                   **MR. CANNON:** Well, the logic, Your Honor, is, if you  
7 have to put something in context, if you have to add color  
8 about what is being displayed here, then you're in the world of  
9 misleading, and you have to prove actual deception.

10                  The category of falsity -- of actual real false data --  
11 that is -- like where the ad has something false in it -- that  
12 is a very specific category. And this doctrine of false by  
13 necessary implication draws into it cases -- cases that would  
14 otherwise be in the misleading category.

15                  And I think if you go back to the original case -- Third  
16 Circuit case -- which was Castrol v. Pennzoil or Pennzoil v.  
17 Castrol -- the necessary implication there was that the  
18 competitor was unnamed. And the apples to oranges cases that  
19 Your Honor is talking about -- that is a different set of  
20 cases.

21                  And the fear, as articulated in the treatise that we  
22 submitted, is when you start to blur the lines between falsity  
23 and misleading, you end up swallowing misleading into false by  
24 necessary implication. And there has to be a line there,  
25 otherwise the presumptions make no sense, and every case would

1 be false by necessary implication. And we know that can't be  
2 the law.

3 **THE COURT:** All right.

4 Brief response, why doesn't the exception swallow the rule  
5 here? Why didn't this conflate the difference between  
6 misleading as opposed to literally false but by implication?

7 **MR. PERLOFF:** Well, Your Honor, in this case, we had  
8 summary judgment, and you considered the facts of this case.

9 There would have to be some feature of the comparison that  
10 would lead a judge, like yourself, to conclude it's false by  
11 necessary implication. And you even mentioned it here. For  
12 example, the undisputed failure to, you know, mention a key  
13 difference between, in this case, the studies or the tests.  
14 And so it wouldn't swallow -- the exception wouldn't swallow  
15 the rule.

16 And with all due respect to Professor McCarthy, every  
17 circuit, that I'm aware of, that has considered this, has  
18 followed the Castrol case, including the Ninth Circuit, as you  
19 well know, because you've relied on it in Southland Sod.  
20 There's no reason to revisit your ruling, Your Honor. Nothing  
21 new has happened, no difference, and your analysis was correct  
22 to begin with.

23 **MR. CANNON:** Your Honor, there is no case from any  
24 circuit or any district court, that I'm aware of, where two  
25 directly comparable products have been led to the false by

1 necessary implication issue here.

2       The apples to oranges cases is always when you have  
3 products that are wildly different. And that is a particular  
4 subset of cases. And I believe the exception would swallow the  
5 rule here if we proceed under the doctrine that any comparison  
6 can be false by necessary implication. It's another way of  
7 saying "misleading."

8       **MR. PERLOFF:** I think that Southland Sod both involved  
9 seeds for grass -- sod.

10       **MR. CANNON:** Southland Sod was not a false by  
11 necessary implication case whatsoever.

12       **MR. PERLOFF:** Well, it actually said a plaintiff may  
13 demonstrate a challenged statement was literally false or false  
14 on its face by necessary implication.

15       But the key, again, is not the nature of the products at  
16 issue or the things at issue. It is the context of the  
17 comparison that's being made. You've considered it here, Your  
18 Honor. Your analysis was correct.

19       **MR. CANNON:** Your Honor --

20       **MR. PERLOFF:** There's no reason to revisit.

21       **THE COURT:** I'm going to end it. I'm going to end it.  
22 You said -- I said one minute. You've gone way over. And  
23 we're running out of time.

24       **MR. CANNON:** I appreciate it, Your Honor. Thank you.

25       **THE COURT:** So let's go to the MoldX questions.

1       It seems to me -- and this is my understanding -- well,  
2 maybe it's not my full understanding -- that there's not a  
3 claim for damages based on these letters -- these  
4 communications -- provided to MolDX, even if they resulted --  
5 contributed -- to the delay in Medicare approval. That's -- I  
6 didn't think that that was within the purview of what was being  
7 sought in this case. This case is about the advertising.

8           **MR. BRAMHALL:** Your Honor, I think you're exactly  
9 right, although Mr. Malackowski, who is Guardant's damages  
10 expert, does purport to opine on the delay as what he calls  
11 "uncalculable [sic] damages." But as Ms. Keller acknowledged  
12 earlier today, neither damages expert -- neither our damages  
13 expert nor Mr. Malackowski -- has any expertise in this issue.

14           This issue should not be part of the case, Your Honor. It  
15 threatens a massive mini trial. The only, quote, "expert" in  
16 the case was a percipient witness offered by Guardant --  
17 Mr. McCoy -- who is their Senior VP of Reimbursement and Client  
18 Services, and he couldn't identify a single shred of evidence,  
19 Your Honor, that Natera did anything that delayed  
20 reimbursement.

21           In fact, MolDX communicated to him, in no uncertain terms,  
22 as confirmed by him and other witnesses at Guardant -- their  
23 executives -- that Natera's comments to MolDX would not be  
24 taken into account in the consideration of Reveal. And we  
25 cited this evidence, Your Honor, in our MIL. This is pages 5

1 to 6. This evidence was -- fully refutes the claim that  
2 Guardant is making. And this is evidence that is testimony  
3 from their 30(b) (6) on this issue. They can't contradict that  
4 evidence, Your Honor.

5 So this issue, as far as we're concerned, is dead. It's  
6 prejudicial. It's made just to inflame the jury. And it's  
7 being offered by experts who they acknowledged today have no  
8 expertise in this field.

9 **THE COURT:** Okay.

10 Response? What's the relevance to this?

11 **MR. SCOLNICK:** Your Honor, the relevance -- we have  
12 numerous points of relevance.

13 But, first, I'd like to put this in the bucket of issues  
14 that's already been decided by the Court. Because, at  
15 Docket 326, page 30, the Court ruled that, quote, "There is  
16 evidence that Natera delayed Medicare coverage for Reveal  
17 through extensive lobbying to MolDX," unquote.

18 As far as relevance, there are additional reasons, as  
19 well. First, this is inextricably intertwined with the rest of  
20 Natera's solar false advertising campaign. And let me tell you  
21 why. The strategy to pressure MolDX was planned, plotted, and  
22 schemed in the same solar meetings, during the same time frame,  
23 with the same Natera employees. In fact, we had -- Ms. Lozano  
24 told us today that Mr. Chapman is intimately involved in  
25 this -- in the communications with MolDX.

1       The communications to MolDX parroted the very same  
2 misleading statements that were sent to oncologists, which this  
3 Court has already ruled a jury could find to be actually false.  
4 MolDX pressure campaign was initiated -- this is important now.  
5 This wasn't by the arm of -- Natera's arm -- of Medicare. This  
6 was a plan that was initiated and plotted by Natera's VP of  
7 Marketing. That's who started this and had the same overall  
8 goal as the rest of Natera's solar campaign, which is to  
9 prevent oncologists and patients from having access to Reveal.

10       So we've got numerous documents involving the same people,  
11 discussing the same campaign, that are some of the core  
12 documents of the case. And it's not fair or practical to  
13 exclude or redact MolDX references in the most central  
14 documents. So that's the first issue, because it's  
15 inextricably intertwined -- first basis of relevance.

16       Second, it goes directly to the credibility of Natera's  
17 witnesses. Now, their witnesses have testified and tried to  
18 justify their false advertisements as a correction of the  
19 record or to protect patients. But these emails and  
20 correspondence about MolDX belie those claims and show that  
21 their attacks and pressure campaign with MolDX was a campaign  
22 in search of justification.

23       And what I mean is this campaign and discussions about  
24 MolDX started months before the Parikh paper came out. And you  
25 can see, they're not even certain what the standards are for

1 MoldX, or why they're attacking it, but they just knew that  
2 they wanted to shut Guardant down. They wanted to prevent us  
3 from having access. They wanted to prevent Medicare patients  
4 from having another opportunity or another option.

5 And it was along the way, weeks and months after that,  
6 that they started coming up with alleged bases to attack  
7 Guardant with MoldX. But this is directly relevant to their  
8 claims that they're going to be putting forward in this case,  
9 and it's directly relevant to the credibility. Guardant --

10 **MR. BRAMHALL:** Your Honor --

11 **MR. SCOLNICK:** -- should not be precluded -- Guardant  
12 should -- excuse me --

13 **THE COURT:** Well, so is the relevance of this to show  
14 state of mind and scienter and culpability and not the actual  
15 effect? In other words, what you're talking about is to show  
16 what their campaign was, what their intent was. Whether that  
17 was successful with MoldX or not, it seems to me that's a  
18 different question.

19 **MR. SCOLNICK:** That was just on point two, Your Honor.  
20 I'm moving on. But the next point is that this is directly  
21 relevant to damages, Your Honor. And contrary to my friend on  
22 the other side -- his assertion -- I don't believe Ms. Keller  
23 stated today that our damages expert has no expertise or  
24 familiarity with MoldX or with the process.

25 On the contrary, he testified, extensively, about the

1 importance of MolDX, about the importance of Medicare approval.  
2 And so have a number of other witnesses in our case. Both of  
3 the founders testified about this --

4 THE COURT: So why wouldn't that get into a "trial  
5 within a trial" 403 problem? That is, now we have to figure  
6 out exactly what happened, why MolDX did what it did, what was  
7 the influential factors looking at all -- suddenly, we're going  
8 to look at why that happened, even though there's no dollar  
9 amount.

10 I understand the argument that, well, maybe this is  
11 relevant to state of mind. They're on a campaign to shut down  
12 Guardant, and that informs why they were fast and loose with  
13 their -- with the solar campaign and the ads and blah, blah,  
14 blah. It goes to culpability, I suppose.

15 But to get into did it really have the effect, and can we  
16 attribute the ultimate outcome of those proceedings to Natera,  
17 as opposed to anybody else who may have commented why MolDX did  
18 what it did, et cetera, et cetera, that seems to me to raise a  
19 trial within a trial, with very limited probative value.

20 MR. SCOLNICK: Your Honor, Natera should not be able  
21 to escape responsibility because this is a slight challenge to  
22 prove this. And I think that --

23 THE COURT: Slight challenge?

24 MR. SCOLNICK: I think it -- I think it's only a  
25 slight challenge. Your Honor has allotted time for both sides.

1 You've given us the total clock. And I'm telling the Court  
2 that I can represent to you we will be able to introduce this  
3 evidence quickly and efficiently within our allotted time. And  
4 this is not so cumbersome or confusing, particularly in light  
5 of the other issues in this case. This is one of the easier  
6 ones.

7 And, Your Honor, I -- forgive -- forgive us, because our  
8 papers don't really lay out the bread crumbs as clearly as we  
9 could have. But there is admissible evidence that doesn't  
10 involve speculation, circumstantial evidence that would  
11 establish that it is more likely than not that Natera's  
12 campaign -- which they admitted was designed to delay and to --  
13 not to delay -- but to sow seeds of doubt and to prevent  
14 Medicare from approving our product -- that it worked.

15 And I can tell you, just very briefly, what those -- what  
16 those dates and important facts are. That in December -- on  
17 December 3rd, 2020, we applied for Medicare coverage. Now,  
18 this was under an expedited TA. Because we were following the  
19 TA that had already been established by -- by Natera. So this  
20 was supposed to be a two-month process. That's what the  
21 testimony in the record is. That's not contradicted.

22 So in February of 2020, MolDX reached out to us and said  
23 that they're waiting for some additional information, but they  
24 want to get things moving as quickly as possible. We still had  
25 the idea this would be done by mid-2020. We submitted our --

1 the final paper -- Harvard paper -- on April 6th. But two days  
2 later, Natera reached out to MolDX and began its campaign of  
3 sowing seeds of doubt.

4 Now, importantly, Your Honor, between December 2020 and  
5 April of 2021, those four or five months, MolDX did not raise  
6 any concerns, objections, or issues with the draft Parikh  
7 paper, which had already been -- which had been submitted for  
8 their review.

9 Now, suddenly, after Natera started making these attacks  
10 on the Parikh Study -- our application -- MolDX began to raise  
11 concerns. And those concerns were the exact same concerns that  
12 Natera -- exact same attacks -- that Natera made on our asset.

13 So you went from a trajectory of green light, everything  
14 looked like it was going to be approved, to all of a sudden  
15 we've got Natera who begins to interfere, and then it's a  
16 yellow light or a red light. And they're raising and parroting  
17 the same exact concerns -- and not concerns -- but attacks that  
18 Natera made and relayed to MolDX.

19 So, ultimately, it was -- MolDX initially denied our  
20 product's approval, and we went back for six or eight months,  
21 and we had to peel back the curtain and look at every single  
22 patient, patient by patient data. And we were eventually able  
23 to substantiate the data in our initial application.

24 And, at that point, in April 2022, which was over a year  
25 after Natera began its campaign to pressure MolDX, at that

1 point, MolDX told us, you know what, we received information  
2 from Natera, but we're not going to allow it to influence our  
3 decision at this point.

4 So that was a year after the -- Natera submitted the --  
5 the initial complaints. So shortly after Natera -- I'm  
6 sorry -- shortly after MolDX told Guardant that they would not  
7 consider that information, we were approved -- in April -- I'm  
8 sorry -- in July of 2022.

9 So there is data. There is admissible evidence --  
10 documentary evidence -- including Natera's own emails,  
11 including internal emails, their communications raising the  
12 same exact attacks that ultimately influenced MolDX. That's in  
13 the record. And it doesn't require any speculation or  
14 conjecture to lay a circumstantial case as to why this  
15 influenced MolDX.

16 **THE COURT:** All right.

17 Let me hear the response.

18 **MR. BRAMHALL:** Sure, Your Honor. So a couple of  
19 things. One, there was an approval in July of 2022. But, to  
20 be clear, it was partial. It wasn't full. There's still no  
21 surveillance approval for Reveal at this point.

22 But, putting that aside, there's nothing simple about  
23 this, Your Honor. As you can see from the description that we  
24 just heard, this is going to involve going down -- to use Your  
25 Honor's phrase -- numerous -- or actually maybe this was

1 Mr. Perloff's phrase -- rabbit holes going forward.

2 This is really, Your Honor, a classic MIL issue. This is  
3 classic 403. It's pure speculation. We have 30(b)(6)  
4 testimony that actually refutes this argument that they're now  
5 trying to contradict. It's highly prejudicial to Natera,  
6 particularly in light of the speculative nature of it. It will  
7 inflame the jury against us and create a massive mini trial if  
8 they're permitted to argue that there was an effect -- a  
9 delay -- we effected Medicare reimbursement to delay. That's  
10 what we're trying to keep out, Your Honor. That's what we  
11 think should stay out.

12 And I would encourage Your Honor to look at the testimony  
13 of Mr. McCoy. This is Exhibit 5 to our MIL. It's transcript  
14 page 190, line 20, to 191, line 10, and page 193, line 10 to  
15 line 22. This is where we directly ask Mr. McCoy whether there  
16 was any evidence of a delay. He wouldn't even use the term  
17 "delay," Your Honor. He just said it took longer than they  
18 expected. And then he said -- and I think this is fatal to the  
19 argument on the other side -- that MoldX said we don't take  
20 into account comments by third parties. We only look at  
21 peer-reviewed evidence. That's the end of this, Your Honor.  
22 There's nothing more.

23 They can speculate, create innuendo and insinuations, but  
24 the reality is, the 30(b)(6) witness on their side has  
25 foreclosed this argument. And to allow the damages expert,

1 who's an accountant, who admitted during his depo he only  
2 learned about MolDX from depositions, to opine on this, is  
3 incredibly prejudicial to Natera. And --

4           **THE COURT:** All right. What about the  
5 admissibility -- what about the admissibility of the  
6 statements -- the letters that were sent -- as part of a -- at  
7 least as portrayed by the plaintiffs -- as a campaign,  
8 consistent with the solar campaign? At least it goes to the  
9 state of mind and the potential motives of Natera.

10           **MR. BRAMHALL:** I think this leads us to the exact same  
11 place, Your Honor. It leads us to the same arguments that are  
12 prejudicial, speculative, and will inflame the jury. And  
13 Mr. McCoy, again, said that MolDX assured them that none of  
14 this would be taken into account.

15           And, Your Honor, if you actually dig into the documents,  
16 the back and forth that went on for years, you can see MolDX  
17 had its own concerns about the Parikh Study. Yes, they matched  
18 up in some places with Natera. But, again, that's proof that  
19 Natera was right and had legitimate concerns about the Parikh  
20 Study. That's not proof that Natera had any comments.

21           There's not a single shred of evidence in the record, Your  
22 Honor, where MolDX says, you know what, Natera really convinced  
23 us of this, or Natera's the reason why we're doing this. That  
24 does not exist. So this should not be presented at trial.

25           **THE COURT:** But the evidence that I'm asking about is

1 the statements made, not the effect. You focused on going --

2 **MR. BRAMHALL:** Sure.

3 **THE COURT:** -- down rabbit holes, the effects of what  
4 did MoldX really consider, was it a causative factor or not,  
5 et cetera, et cetera. And I -- I tend to agree with that, for  
6 the reasons I stated at the outset.

7 On the other hand, I think it's a pretty good argument  
8 that at least any statements made, to whomever, often is used  
9 to show state of mind of the speaker. And the speaker here  
10 happens to be the defendant.

11 So I'm having a harder time -- even if we were to say  
12 we're not going to go into effects and what MoldX was thinking,  
13 et cetera, et cetera, but just that the statements were made.  
14 At least the other side was going to try to portray it as part  
15 of a campaign mindset.

16 **MR. BRAMHALL:** Your Honor, I'd suggest that it's not  
17 probative of anything. And it's highly prejudicial, even to  
18 allow for that purpose. Because what Guardant's going to do --  
19 and they said this in their briefing -- is to point out the  
20 timing of our comments and then the timing of reimbursement.  
21 And then they'll make the same argument about how they thought  
22 it should be two months to suggest to the jury -- to get the  
23 jury in their minds to say, wow, Natera really messed up this  
24 reimbursement. Natera is the cause. We're going to end up in  
25 the same prejudicial place, Your Honor.

1       They don't -- they don't need this evidence -- and let me  
2 back up. This is about whether their test met the criteria  
3 under a statutory -- the statutory framework -- of Medicare  
4 reimbursement. That has nothing to do with false advertising,  
5 commercial promotion, or anything else. That is a completely  
6 separate issue that Natera was frankly justified in raising  
7 concerns about. Because, as you heard, Natera was the one who  
8 went through a year's-long process to get their test approved  
9 first, and then Guardant followed suit afterwards.

10       **THE COURT:** So if the --

11       **MR. BRAMHALL:** Natera -- sorry.

12       **THE COURT:** If what MolDX did, and why they did it, is  
13 off the table, and that evidence is barred, I'm not sure I see  
14 that -- that same 403 problem. Yeah, it's prejudicial.  
15 Anything somebody says could be prejudicial if cast in a  
16 certain light. But this has got to be unduly prejudicial, and  
17 I'm not sure that it is.

18       **MR. BRAMHALL:** I'm just worried, Your Honor, we're  
19 going to end up in the exact same place with the undue  
20 prejudice. Because the suggestion is going to be -- and,  
21 again, they said it in their brief -- that they're going to let  
22 the jury come to their own conclusions that Natera was the  
23 cause of the delay.

24       And, again, Your Honor, if we -- perhaps if the expert is  
25 not allowed to opine on this at all, maybe then it's less of an

1 issue with just there's some discussion of the fact that Natera  
2 reached out to MoldX and raised these legitimate concerns.

3 Sure, we can explain that. But then the expert should not be  
4 able to talk about this in the context of damages.

5 **THE COURT:** Well, I agree. I -- that's what I'm  
6 saying. I would exclude any reference to what MoldX did. And  
7 the expert can't say, well, there was a delay, and that makes  
8 it conservative. As far as I'm concerned, the jury doesn't  
9 have to know that there was any delay. All they need to know  
10 is that there was at least an effort on Natera's part to weigh  
11 in on this process, which the other side will portray is  
12 consistent with their motive of trying to squelch this product.

13 **MR. BRAMHALL:** Yeah. And, Your Honor, I think I've  
14 raised my concerns with this if that's where Your Honor is  
15 leaning. But we're keeping the effect out. I think that would  
16 address a lot of the prejudice, frankly. I'm still concerned.  
17 And maybe we'd have to watch very carefully as this develops at  
18 trial. But I understand where Your Honor is coming from on  
19 that.

20 **MR. SCOLNICK:** And if I could just briefly respond,  
21 Your Honor. I agree that it's admissible for all the reasons I  
22 stated. And of course it's prejudicial. But it's prejudicial  
23 because this -- it's nefarious -- what they tried to do. It  
24 was inappropriate. It was improper. So the issue --

25 **THE COURT:** Well, I mean, I understand -- I'm not the

1 jury. So you can make that argument to the jury. But --

2 MR. SCOLNICK: Okay.

3 THE COURT: I understand your position.

4 Okay.

5 MR. SCOLNICK: So the issue with -- I'm sorry.

6 THE COURT: Well, go ahead.

7 MR. SCOLNICK: With respect to causation, Your Honor,

8 Mr. McCoy testified the way he did because he wasn't -- he

9 wasn't privy to all the documents that were sent to MoldX by

10 Natera. That is attorneys' eyes only. So had he seen that --

11 had he been able to opine the similarities of the same exact

12 issues and attacks that Natera was making were reiterated by

13 MoldX, then it would make sense.

14 And I think that there's certainly enough here for the  
15 jury to -- to get the jury -- so the jury can make their own  
16 conclusions. And certainly the attacks and criticisms that my  
17 friend is making on the other side can be levied to the jury.  
18 But let them have -- let the jury come to the decision. That's  
19 my argument, Your Honor.

20 And I think that -- out of fairness and transparency --  
21 that we should be able to present our entire case and --  
22 including the multiple witnesses who already testified that  
23 there has been a delay -- and this is not typical -- and for  
24 all the reasons and circumstances that have been cited, that is  
25 more likely than not that that delay was caused or influenced

1 by Natera. And that's what we're seeking to admit.

2           **THE COURT:** All right. I kind of want to get to  
3 Number 3, but I'm afraid, once we start, it's going to take  
4 more than the three minutes I have left.

5           So what I want to do is continue this. We've got to talk  
6 about this, the jury instructions, some of the bellwethers, and  
7 of course when our start date is going to be. Still on the  
8 table, I think, is April 29 and July 29. I know there's some  
9 conflicts there, and I know this interferes with various plans,  
10 but at least those were the two that I had mentioned last time.  
11 So I'm just reminding you of that.

12           So let's reconvene on -- I think I have time on Friday.  
13 Let me make sure that's true. Because I want to get through as  
14 much of this as I can so you have -- you know exactly what's  
15 coming down the pike here. So why don't we say 10:00 on  
16 Friday.

17           **MR. JOHNSON:** That's fine with us.

18           **THE COURT:** Pacific Time. And hopefully this won't  
19 take more than a couple hours. We should be done by noon, is  
20 my open hope. Okay?

21           **MR. JOHNSON:** Sounds good from the Natera side.

22           **THE COURT:** All right. Okay. So we'll see you then.  
23 I appreciate your cooperation in scheduling this.

24           All right. Thanks, everyone. See you on Friday.

25           **MR. JOHNSON:** Thank you, Your Honor.

1 MR. PERLOFF: Thanks for your time.

2 THE CLERK: Court is adjourned.

3 (The proceedings adjourned 6:12 p.m.)

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6 CERTIFICATE OF REPORTER

7 I certify that the foregoing is a correct transcript  
8 from the record of proceedings in the above-entitled matter.

9

10 DATE: Thursday, February 29, 2024

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12 Kendra Steppler

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14 Kendra A. Steppler, RPR, CRR

15 Official Reporter, U.S. District Court

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